

IN THE DISTRICT COURT OF APPEAL  
FIRST DISTRICT, STATE OF FLORIDA

Case No. 1D19-1781  
Lower Tribunal Case Nos.: DOAH 18-4473; DOH 18-0174

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LOUIS DEL FAVERO ORCHIDS, INC.,

Appellant,

v.

FLORIDA DEPARTMENT OF HEALTH, an executive branch agency of the  
State of Florida and PERKINS NURSERY, INC.

Appellees.

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**APPENDIX TO APPELLANT'S MOTION TO CONSOLIDATE AND  
EXPEDITE APPEALS**

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Seann M. Frazier  
Florida Bar No. 971200  
Marc Ito  
Florida Bar No. 61463  
Kristen Bond  
Florida Bar No. 118579  
215 South Monroe Street, Suite 750  
Tallahassee Florida 32301  
(850) 681-0191  
sfrazier@phrd.com  
mito@phrd.com  
kbond@phrd.com  
*Counsel for Louis Del Favero Orchids, Inc.*

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PARKER HUDSON RAINER & DOBBS, LLP

/s/ Seann M. Frazier

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Seann M. Frazier

Florida Bar No. 971200

Marc Ito

Florida Bar No. 61463

Kristen Bond

Florida Bar No. 118579

215 South Monroe Street, Suite 750

Tallahassee Florida 32301

(850) 681-0191

[sfrazier@phrd.com](mailto:sfrazier@phrd.com)

[mito@phrd.com](mailto:mito@phrd.com)

[Kbond@phrd.com](mailto:Kbond@phrd.com)

Counsel for Louis Del Favero Orchids, Inc.

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on June 17, 2019, a copy of the foregoing was filed with the Florida Courts E-Portal which will furnish copies to its registered users, including the following:

James A. McKee  
Benjamin J. Grossman  
Nicholas J.P. Meros  
Foley & Lardner LLP  
106 E. College Avenue, Suite 900  
Tallahassee, FL 32301  
jmckee@foley.com  
mlong@foley.com  
bjgrossman@foley.com  
cforjet@foley.com  
nmeros@foley.com  
bhurn@foley.com  
Counsel for Perkins Nursery, Inc.

Eduardo S. Lombard  
Radey Law Firm  
301 S. Bronough Street, Suite 200  
Tallahassee, Florida 32301  
Elombard@radeylaw.com  
Counsel for Department of Health

Louise R. Wilhite-St. Laurent  
4052 Bald Cypress Way Bin A02  
Tallahassee, FL 32399  
louise.stlaurent@flhealth.gov  
Counsel for Department of Health

/s/ Seann M. Frazier  
Seann M. Frazier  
Florida Bar No. 971200

**STATE OF FLORIDA  
DIVISION OF ADMINISTRATIVE HEARINGS**

SPRING OAKS GREENHOUSES, INC.,

Petitioner,

Case No. 18-4471

vs.

DEPARTMENT OF HEALTH, OFFICE  
OF MEDICAL MARIJUANA USE,

Respondent.

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**THE DEPARTMENT'S NOTICE OF FILING**

Respondent Florida Department of Health files in this matter the attached *Reply to Petitioners' Joint Response to September 7 Order*, originally filed in DOAH Case No. 18-4463.

**CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing was served on September 24, 2018, by email to:

John M. Lockwood  
Thomas J. Morton  
Devon Nunneley  
The Lockwood Law Firm  
106 East College Avenue, Suite 810  
Tallahassee, Florida 32301  
john@lockwoodlawfirm.com  
tj@lockwoodlawfirm.com  
devon@lockwoodlawfirm.com

*Counsel for Spring Oaks Greenhouses, Inc.*

*/s/ Eduardo S. Lombard*

---

Eduardo S. Lombard  
Florida Bar No. 0153590  
Megan S. Reynolds  
Florida Bar No. 0042000

Vezina, Lawrence & Piscitelli, P.A.  
413 East Park Avenue

Tallahassee, Florida 32301  
(850) 224-6205  
elombard@vlplaw.com  
mreynolds@vlplaw.com  
rhodge@vlplaw.com

*Counsel for Respondent Department of  
Health*

**STATE OF FLORIDA  
DIVISION OF ADMINISTRATIVE HEARINGS**

DEWAR NURSERIES, INC.,

Petitioner,

vs.

Case No. 18-4463

FLORIDA DEPARTMENT OF HEALTH,  
an executive branch agency of  
the State of Florida,

Respondent.

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**THE DEPARTMENT’S REPLY TO PETITIONERS’  
JOINT RESPONSE TO SEPTEMBER 7 ORDER**

Pursuant to the ALJ’s order dated September 7, 2018, Respondent Florida Department of Health submits this reply to Petitioners’ *Joint Brief in Response to September 7, 2018 Order*.

**Introduction**

Resolution of these matters turns almost entirely on interpretation of a statutory provision found in section 381.986, Florida Statutes (2017), Florida’s primary medical-marijuana statute. Petitioners each claim that they qualify under a specific and narrow provision of law for one of a very limited number of medical marijuana treatment center (MMTC) licenses. To be sure, none of the petitioners qualifies, as explained in the Department’s denial letters attached to the petitions. Nevertheless, in the context of the Department’s request for consolidation, Petitioners object to consolidation if done for purposes of conducting an *Ashbacker* comparative hearing. Cutting straight to the matter, if Petitioners do not want an *Ashbacker* hearing, the Department will not at this time insist that one is required. Because the Department contends that none of the petitioners qualifies for licensure, the Department is willing to proceed immediately to a final hearing that will not involve comparative review of Petitioners’ licensure applications.

Still, and without regard to the number of available licenses, the matters should be consolidated. Seven petitioners will want to take depositions of an agency representative, and an agency representative will likely be required to testify seven times on the same facts and issues. There is, frankly, little to nothing unique about each petition. The potential burden on the State's witness outweighs the minor impact (if any) on Petitioners. The number of available licenses is, today, immaterial to consolidation. Therefore, the matters should be consolidated for discovery and trial; however, the ALJ should issue separate recommended orders for consideration by the Department in issuing its final orders on each petition for licensure.

#### **Objection to DOAH Reaching Conclusions of Law Outside of a Recommended Order**

In these matters challenging licensure denials, DOAH is charged with resolving disputed facts and suggesting in a recommended order a disposition based on those facts. The parties may submit written exceptions to the recommended order to attempt to convince the Department that part or all of recommendation was incorrect or should not be adopted. *See* § 120.57(1)(k), Fla. Stat. (2018).<sup>1</sup> The Department must then consider each finding of fact and conclusion of law in the recommended order and consider each exception when issuing its final order. *See* § 120.57(1)(l), Fla. Stat. To the extent DOAH has requested briefing on the legal question of how many MMTC licenses are available under the law, that issue must be resolve in the ordinary course under section 120.57(1), Florida Statutes, through entry of a recommended order on the issue such that each petitioner or the Department may exercise its rights under statute to take exception. Therefore, the Department objects to DOAH reaching any conclusion of law that affects the merits of these matters outside of a recommended order. Such conclusions must be included in a recommended order.

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<sup>1</sup> All citations to statutes in this response refer to the 2018 version of the Florida Statutes unless otherwise indicated.



## **The Compassionate Medical Cannabis Act of 2014**

The Florida Legislature has charged the Department with administering and enforcing laws relating to the general health of the people of the State. *See* § 381.0011(2), Fla. Stat. The legislature has also charged the Department with special responsibility for implementing and enforcing the Compassionate Medical Cannabis Act of 2014. *See, e.g.*, chapter 2014-157, Laws of Fla.

In 2014, the legislature passed the Compassionate Medical Cannabis Act of 2014 (the 2014 Act). *See, e.g., id.* (pertinent portions codified at section 381.986, Florida Statutes). The 2014 Act provided for the regulation and use of low-THC cannabis. *See generally id.* The 2014 Act authorized licensed physicians to order low-THC cannabis for qualified patients under specified conditions (primarily cancer and other debilitating conditions that produce severe and persistent seizures and muscle spasms). *See generally id.* The 2014 Act directed the Department to authorize only five exclusive “dispensing organizations” (DOs)—one in each of five regions: Northwest, Northeast, Central, Southeast, and Southwest Florida. *See id.* § 2(5)(b). The 2014 Act set forth a general framework for an application process in which the Department would determine which statutorily qualified applicant was the most dependable and most qualified for each region. *See id.*

### **The 2014 and 2015 Rules**

The 2014 Act also empowered the Department to adopt rules to implement the 2014 Act. *See* § 381.986(5)(d), Fla. Stat. (2014). The Department’s first set of proposed rules under the 2014 Act was determined to be an invalid exercise of delegated legislative authority, in part on the basis that the rules did not provide for a comparative review of DO applications—the type of review DOAH concluded was required by the 2014 Act as a matter of law. *See Costa Farms, LLC v. Dep’t of Health*, Case Nos. 14-4296RP, 14-4299RP, 14-4517RP, 14-4547RP, ¶¶ 80–96 (Fla.

DOAH Nov. 14, 2014) (*Costa* Final Order). DOAH’s final order invalidating those rules stated that the Department’s application evaluation must entail a comparison of applicants because the number of available licenses was limited. *See id.*

The Department then developed, and in 2015 formally adopted, detailed rules implementing the application, selection, and regulatory processes for licensees. *See Fla. Admin. Code Ch. 64-4 (2015); Baywood Nurseries Co. v. Dep’t of Health*, Case No. 15-1694RP, ¶ 10 (Fla. DOAH May 27, 2015) (*Baywood* Final Order). Rule 64-4.002 (2015) incorporated by reference an *Application for Low-THC Cannabis Dispensing Organization Approval* and a *Scorecard for Low-THC Cannabis Dispensing Organization Selection* for use by the applicants and the application evaluators, respectively. *See Fla. Admin. Code R. 64-4.002 (2015)*. The Department’s second attempt to adopt rules in Florida Administrative Code Chapter 64-4 (2015) was also challenged. *See generally Baywood* Final Order, DOAH Case No. 15-1694RP. ALJ Watkins issued a final order determining the 2015 rules to be valid in their entirety. *See generally id.*

### **The 2015 Application Batch**

In reliance on the *Baywood* Final Order, the Department proceeded with the 2015 DO-license application batch. *See, e.g., Loop’s Nursery & Greenhouses, Inc. v. Dep’t of Health, Office of Compassionate Use*, DOAH Case No. 15-7274, Final Order at 33 ¶ 1 (adopting Rec. Order ¶ 2) (Fla. DOAH Oct. 7, 2016; Fla. DOH Jan. 5, 2017) (*Loop’s* Final Order).

The requirements to become a licensed medical-marijuana “dispensing organization” (DO) were set forth in section 381.986, Florida Statutes (2014), and Florida Administrative Code Rules 64-4.001 and 64-4.002 (2015). To be approved as a region’s exclusive DO, an applicant needed to demonstrate to the Department not only that the applicant met the basic statutory requirements, but also that it was the most qualified—or “the best”—applicant in a given region to further the Department’s special responsibility to ensure reasonable statewide accessibility and availability of

low-THC cannabis as necessary for qualified patients. *See* § 381.986(5)(b), Fla. Stat. (2014); *Costa* Final Order, Case Nos. 14-4296RP, 14-4299RP, 14-4517RP, 14-4547RP, ¶¶ 76–77; *Baywood* Final Order, Case No. 15-1694RP, ¶ 7.

Rule 64-4.002 (2015), the incorporated application form, and the incorporated scorecard contained five categories and several subcategories. *See* Fla. Admin. Code R. 64-4.002 (2015). The categories and subcategories contained over 150 individual items or topics that would help the Department assess each applicant’s ability to satisfy the seven statutory requirements and prove to the Department that the applicant was better than the other applicants in the same region. *See id.*

The application also set forth the scoring system the Department’s evaluators would use to independently evaluate applications, including the weighting system that would be applied. *See id.* The Department’s scorecard also listed each category, subcategory, and item or topic, that would be scored. *See id.* § (5)(a). Under rule 64-4.002 (2015), the scores from each evaluator’s scorecard for a particular applicant would be combined to generate an aggregate score for the applicant, and the applicant with the highest aggregate score in each region would be approved as the region’s DO. *See id.*

### **The DO-Application Process**

The DO-license-application process was set forth in section 381.986 (2015) and rules 64-4.001 and 64-4.002 (2015). Applicants were directed to submit a completed application, including the application fee, no later than July 8, 2015.<sup>2</sup> *See* Fla. Admin. Code R. 64-4.002(5) (2015). In July 2015, approximately 28 applicants submitted applications to become the exclusive DO in one

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<sup>2</sup> Rule 64-4.002(5) (2015) provided that applications were due no later than 21 days after the effective date of the rule, which became effective June 17, 2015.

of the five regions. Petitioners were among those applicants.

Within its application, each applicant was required to provide a written explanation or provide written documentation, as applicable, showing how the applicant met the statutory requirements, addressing each item listed in rule 64-4.002 (2015). *See, e.g., Baywood* Final Order, DOAH Case No. 15-1694RP, ¶ 57. All timely filed applications were initially reviewed by the Department for compliance with the minimum statutory requirements. *See, e.g., See Loop's* Final Order, DOAH Case No. 15-7274, Final Order at 33 ¶ 1 (adopting Rec. Order ¶ 23). If it was determined there were any deficiencies, the Department sent the applicant a certified letter identifying the deficiency and providing a deadline for the applicant to correct the deficiency, usually by providing additional information or documentation. *See, e.g., id.* (adopting Rec. Order ¶ 23).

After the applicants had the opportunity to correct any deficiencies, the evaluators independently evaluated and scored the applications, *See, e.g., id.* (adopting Rec. Order ¶¶ 25–26), applying rule 64-4.002 (2015)'s provisions and the scorecard as they were required by law to do, Fla. Admin. Code R. 64-4.002(5) (2015). The evaluation was performed by comparing the applications against each other in each region to determine which applicant was the best in the categories and subcategories. *See, e.g., See Loop's* Final Order, DOAH Case No. 15-7274, Final Order at 33 ¶ 1 (adopting Rec. Order ¶¶ 25–26). The scores were then compiled in a spreadsheet that calculated each applicant's aggregate score and ranking in its region. *See, e.g., id.* (adopting Rec. Order ¶ 26). Importantly, because each applicant's final score was an aggregate score, having the highest score in its region for a particular category, such as cultivation, did not make an applicant the best candidate to be that region's DO. *See, e.g., id.* Instead, it was an applicant's *overall* quality as determined by the Department's aggregate scores that dictated whether the

applicant was “the best.” *See, e.g., id.*

Consistent with the rules validated by ALJ Watkins, the Department calculated applicants’ scores by entering the section and subsection scores assigned by the individual evaluators into the spreadsheet to produce a “Final Rank” and a “Regional Rank” for each applicant whose application was reviewed, evaluated, and scored (the Final Scorecard). *See, e.g., id.* The applicants’ scores by evaluator, Final Rank, and Regional Rank are reflected in the Final Scorecard’s summary worksheet as follows:

Applicant	Region	Reviewer 1	Reviewer 2	Reviewer 3	Final Rank	Regional Rank
3 Boys	Southwest	2.6875	3.1000	4.6125	3.4667	4
Alpha	Southwest	4.8750	3.5000	3.9375	4.1042	5
Perkins	Southwest	1.3750	2.0375	2.9375	2.1167	1
Plants of Ruskin	Southwest	2.7625	2.3375	2.8375	2.6458	2
Sun Bulb	Southwest	3.3000	4.0250	2.1500	3.1583	3
Bill's	Southeast	2.1125	1.1500	1.3875	1.5500	1
Costa	Southeast	4.2750	4.2375	4.6875	4.4000	5
Keith's St. Germain	Southeast	2.4125	4.1250	3.1000	3.2125	4
Nature's Way	Southeast	2.4500	3.4875	2.7125	2.8833	2
Redland	Southeast	3.7500	2.0000	3.7750	3.1750	3
Deleon	Central	1.8375	2.8875	1.0000	1.9083	1
Dewar	Central	4.7500	4.5750	2.5375	3.9542	3
Knox	Central	4.1750	6.5875	5.8750	5.5458	7
McCrary's	Central	5.4125	4.6875	6.5250	5.5417	6
Redland	Central	6.4000	2.3375	4.5500	4.4292	4
Spring Oak	Central	1.4375	1.3750	3.3125	2.0417	2
Treadwell	Central	3.9875	5.4375	4.2750	4.5667	5
Bill's	Northeast	1.2500	1.4250	1.0000	1.2250	1
Chestnut Hill	Northeast	4.7250	3.6500	3.0000	3.7917	4
Hart's	Northeast	3.2375	2.0750	2.0000	2.4375	2
Loop's	Northeast	2.7250	3.9875	4.0000	3.5708	3
San Felasco	Northeast	3.0625	3.8625	5.0000	3.9750	5
Alpha	Northwest	3.3125	2.9000	2.0000	2.7375	3
Hackney	Northwest	3.6125	3.4500	4.0000	3.6875	4
Hart's	Northwest	1.7250	1.9250	3.0000	2.2167	2
Tree King	Northwest	1.3500	1.7250	1.0000	1.3583	1

*E.g., Fla. S. Comm. on Approp., SB 8-A (2017) Staff Analysis at 6 (Staff Analysis attached as Exhibit A).*

Applicants with the highest Final Ranking in each region were deemed approved (that is, the winners) for their respective regions. The Regional Rank reflects an applicant’s place in within

its region, with the highest Regional Rank being the best and the lowest regional rank reflecting the worst application. *See* Ex. A. For example, in the Southwest region, Alpha Foliage had the highest (and best) Final Rank of 4.1042 and Regional Rank of 5. *See* Ex. A. Perkins received the Southwest region's lowest (and worst) Final Rank of 2.1167 and was last with a Regional Rank of 1. *See* Ex. A.

### **The 2015 Point of Entry**

The Department notified each losing applicant by letter dated November 23, 2015, that the applicant was not the highest-scored applicant for its region and therefore its application was denied (the 2015 Denial Letters). *See, e.g.*, Dewar Pet. Ex. B. The 2015 Denial letters included the following notice of chapter 120 rights:

This notice is agency action for purposes of section 120.569, Florida Statutes. A party whose substantial interest is affected by this action may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. A petition must be filed in writing and must be received by the Agency Clerk within twenty-one (21) days from receipt of this notice. The petition may be mailed to the Agency Clerk, Department of Health, 4052 Bald Cypress Way, BIN #A-02, Tallahassee, FL 32399-1703; hand delivered to the Agency Clerk, Department of Health, 2585 Merchants Row Blvd., Prather Building, Suite 110, Tallahassee, FL; or sent by facsimile to (850) 413-8743. Such petition must be filed in conformance with Florida Administrative Code Rules 28-106.201 or 28-106.301, as applicable.

Mediation is not available.

**Failure to file a petition within 21 days shall constitute a waiver of the right to a hearing on this agency action.**

*See, e.g.*, Dewar Pet. Ex. B.

Although the 2015 Denial Letters did not include scores, the scores for all applicants were used to make the decision to grant or deny a particular license. Further, the applicants' scores were public record, provided to many applicants and non-applicants in response to public records requests.

### **The 2015 License Challenges**

In December 2015, the Department received 13 petitions from disappointed license applicants, including Petitioners Dewar Nurseries, Inc.; Tree King–Tree Farm, Inc.; Perkins Nursery, Inc.; and TropiFlora, LLC. All petitions were referred to DOAH. Dewar, Tree King, Perkins, and TropiFlora voluntarily dismissed their petitions prior to final hearing. *See In re License of the Low-THC Cannabis Dispensing Organization for the Southwest Region*, DOAH Case Nos. 15-7269, 15-7270, 15-7271, 15-7272; *Dewar Nurseries, Inc. v. Dep’t of Health*, DOAH Case No. 15-7273; *Tree King–Tree Farm, Inc. v. State of Fla., Fla. Dep’t of Health*, DOAH Case No. 15-7278. Petitioners Bill’s Nursery, Inc.; Deleon’s Bromeliads, Inc.; and Spring Oaks Greenhouses, Inc., failed to avail themselves of the point of entry provided in the 2015 Denial Letters. Four other applicants proceeded to final hearing, and those matters were resolved by final order. *See, e.g., Loop’s Final Order*, DOAH Case No. 15-7274; *McCrorry’s Sunny Hill Nursery, LLC v. Dep’t of Health*, Case No. 15-7275 (Fla. DOAH Dec. 12, 2016; Fla. DOH Dec. 19, 2016); *Plants of Ruskin, Inc. v. Dep’t of Health*, Case Nos. 17-0116, 17-0117 (Fla. DOAH May 23, 2017; Fla. DOH Aug. 22, 2017).

### **The Constitutional Amendment**

Effective January 3, 2017, the Florida Constitution was amended to include article X, section 29, titled *Medical marijuana production, possession and use* (the Amendment). The purpose of the Amendment (as reflected by the statement of public policy found at the beginning of the Amendment) was to exempt qualifying patients and caregivers, qualifying physicians, and the Department and its employees and agents from criminal liability for their actions relating to medical marijuana—so long as those persons comply with Department regulations and applicable regulatory statutes. *See art. X, § 29(a)(1)–(3), Fla. Const.*

Among other things, the Amendment (1) allows for the establishment of MMTCs to

cultivate, process, and dispense medical marijuana and (2) authorizes the use of full-strength-THC medical marijuana by qualified patients with a broader range of medical conditions—all subject to Department regulations and other statutory provisions. *See* art. X, § 29, Fla. Const. The Amendment empowers the Department to “issue reasonable regulations necessary for the implementation and enforcement of this section. The purpose of the regulations is to ensure the availability and safe use of medical marijuana by qualifying patients.” *See id.* § (d).

The Amendment also provides, “Nothing in this section shall limit the legislature from enacting laws consistent with this section.” *See id.* § (e).

### **The New 2017 Law**

In a 2017 special session, the legislature completely rewrote section 381.986 (2016) (the 2017 Law). *See* ch. 2017-232, § 3, Laws of Fla. The 2017 Law repealed the DO Law in its entirety. *See, e.g., id.* In its place, the legislature provided a comprehensive regulatory structure to implement the constitutional amendment. *See, e.g., id.* However, the 2017 Law did provide for former DOs to receive MMTC licenses upon meeting certain statutory requirements<sup>3</sup>:

[T]he department shall license as a medical marijuana treatment center any entity that holds an active, unrestricted license to cultivate, process, transport, and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices, under former s. 381.986, Florida Statutes 2016, before July 1, 2017, and which meets the requirements of this section.

§ 381.986(8)(a)1, Fla. Stat. (2017). But on the whole, the 2017 Law does not allow for unlimited licenses.

First, only those DOs licensed when the 2017 Law became effective were eligible to obtain MMTC licenses, if they otherwise met the regulatory requirements of the 2017 Law. *See, e.g.,* § 381.986(8)(a)1, Fla. Stat. (2017). Then, a batch of 10—and only 10—licenses was permitted to

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<sup>3</sup> The 2017 Law also authorizes the use of full-strength-THC medical marijuana by qualified patients with a broader range of medical conditions.



be issued by the Department to applicants meeting the following conditions and requirements:

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(a) . . .

2. The department shall license as medical marijuana treatment centers **10 applicants that meet the requirements of this section, under the following parameters:**

a. As soon as practicable, but no later than August 1, 2017, the department shall license any applicant whose application was reviewed, evaluated, and scored by the department and which was denied a dispensing organization license by the department under former s. 381.986, Florida Statutes 2014; which had one or more administrative or judicial challenges pending as of January 1, 2017, **or had a final ranking within one point of the highest final ranking in its region under former s. 381.986, Florida Statutes 2014; which meets the requirements of this section;** and which provides documentation to the department that it has the existing infrastructure and technical and technological ability to begin cultivating marijuana within 30 days after registration as a medical marijuana treatment center.

b. As soon as practicable, the department shall license one applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011). An applicant licensed under this sub-subparagraph is exempt from the requirement of subparagraph (b)2.

§ 381.986(8)(a)2.a–b, Fla. Stat. (2017) (emphasis added).

The legislature then reiterated that no more than 10 licenses could be issued when the legislature directed the Department to accept applications as necessary to fill the 10 slots:

c. As soon as practicable, but no later than October 3, 2017, the department shall license applicants that meet the requirements of this section **in sufficient numbers to result in 10 total licenses issued under this subparagraph, while accounting for the number of licenses issued under sub-subparagraphs a. and b.**

§ 381.986(8)(a)2.c, Fla. Stat. (2017) (emphasis added).

And within such future application batch to round out the 10 licenses, the Department was to give a preference for up to two of the license applicants:

3. For up to two of the licenses issued under subparagraph 2., the

department shall give preference to applicants that demonstrate in their applications that they own one or more facilities that are, or were, used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses and will use or convert the facility or facilities for the processing of marijuana.

§ 381.986(8)(a)3, Fla. Stat. (2017).

The legislature once again reiterated that the licensing structure is *limited* when the legislature provided that *if and when* the patient registry reached 100,000 active patients, the Department would be required to issue 4 more licenses:

4. Within 6 months after the registration of 100,000 active qualified patients in the medical marijuana use registry, the department shall license **four additional medical marijuana treatment centers** that meet the requirements of this section. Thereafter, the department shall license four medical marijuana treatment centers within 6 months after the registration of each additional 100,000 active qualified patients in the medical marijuana use registry that meet the requirements of this section.

§ 381.986(8)(a)4, Fla. Stat. (emphasis added).

In simple terms, then, the 2017 Law directed the Department to (1) issue MMTC licenses to those entities that already possessed DO licenses under the old (and now repealed) law and that satisfied the new law's requirements; (2) issue an additional 10 licenses—and only 10 licenses—as provided in section 381.986(8)(a)2, Florida Statutes (2017), with one reserved exclusively for *Pigford/BFDL* class applicants, and with a preference for up to two “citrus” applicants; and (3) issue 4 more licenses sometime in the future, if and when the patient registry hits 100,000 active patients (and 4 more for every additional 100,000 active patients). *See* § 381.986(8)(a)1–4, Fla. Stat. (2017).

**Petitioners' arguments are flawed and invite the ALJ to rewrite the statute.**

Petitioners' contention that the number *10* as used in section 381.986(8)(a)2 (2017) is just a minimum is mistaken. As a state executive agency, the Department's powers are limited to those granted by the legislature and the Florida Constitution. *See, e.g., State of Fla., Dep't of Env'tl.*

*Regulation v. Puckett Oil Co.*, 577 So. 2d 988, 991 (Fla. 1st DCA 1991); *cf. Decker v. Univ. of W. Fla.*, 85 So. 3d 571, 573 (Fla. 1st DCA 2012). The legislature did not direct the Department to issue “at least 10” licenses or “10 or more” licenses; the legislature authorized 10 licenses to be issued under section 381.986(8)(a)2, period. This is a matter of simple statutory construction. When Petitioners argue that section 381.986(8)(a)2.a’s phrase *shall license any applicant* means the number 10 is a minimum, Petitioners ask DOAH to (impermissibly) delete the number 10 from the statute, *see, e.g., Westphal v. City of St. Petersburg*, 194 So. 3d 311, 321 (Fla. 2016) (“Although this Court must, whenever possible, construe statutes to effect a constitutional outcome, we may not salvage a plainly written statute by rewriting it.”).

When Petitioners filed their petitions in these matters, the Department had issued 7 of the 10 MMTC licenses under section 381.986(8)(a)2 (2017). This leaves only 3 of 10 spots available for licensure under section 381.986(8)(a)2 (2017). Of those 3, one is reserved for *Pigford* applicants. *See* § 381.986(8)(a)2.b, Fla. Stat. (2017). That leaves only 2 licenses, if any at all, available for Petitioners. Again, the Department contends none of the petitioners is qualified and that the remaining 2 licenses are to be awarded through a separate application batch.

Additionally and contrary to Petitioners’ contention, section 381.986(8)(a)2.a (the One-Point Provision) does not apply to the additional 4 licenses under the separate and distinct section 381.986(8)(a)4.<sup>4</sup> The One-Point Provision authorizes licenses from the pool of 10 licenses under *section 381.986(8)(a)2 only*. *See* § 381.986(8)(a)2, Fla. Stat. (2017). This, too, is a matter of simple statutory construction. Indeed, when directing the Department to issue licenses under the

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<sup>4</sup> In fact, the Department has promulgated rules applicable to the additional 4 licenses available under section 381.986(8)(a)4—rules that are separate from the rules applicable to licensure under the One-Point Provision and that reflect the Department’s interpretation of section 381.986, its own statute.

One-Point Provision by August 2017, the legislature knew that the patient registry had not reached 100,000 active patients, and the legislature could not know when that would occur. In fact, it defies plain logic to argue that the legislature ordered that licenses be issued under the One-Point Provision by August 2017 but at the same time directed that some of those licenses be drawn from a set of 4 licenses sometime in the future, after August 2017.

Importantly, an administrative agency’s interpretation of the statute the agency is charged with implementing is entitled to great deference. *See, e.g., Level 3 Commc’ns, LLC v. Jacobs*, 841 So. 2d 447, 450 (Fla. 2003); *Shands Jacksonville Med. Ctr., Inc. v. Dep’t of Health*, Case No. 17-3265, Final Order at 2 (adopting Rec. Order ¶¶ 83–84) (Fla. DOAH June 13, 2018; Fla. DOH July 19, 2018) (Chief ALJ Cohen). Reviewing courts and DOAH will not depart from the contemporaneous construction of a statute by a state agency charged with the statute’s implementation and enforcement. *See, e.g., Level 3*, 841 So. 2d at 450; *Shands*, DOAH Case No. 17-3265, Final Order at 2 (adopting Rec. Order ¶¶ 83–84). DOAH must defer as well. *See Shands*, DOAH Case No. 17-3265, Final Order at 2 (adopting Rec. Order ¶¶ 83–84).

**The legislative record supports the Department’s interpretation.**

To be sure, none of the petitioners qualifies for licensure, as explained in the Department’s denial letters attached to the petitions. Indeed, none is within one point of the highest-ranking applicant in the 2015 DO-application batch, whether using the Final Rank or the Regional Rank:

Region	Applicant	Status	Final Rank	Regional Rank
Central	<b>Knox</b>	<b>Winner</b>	<b>5.5458</b>	<b>7</b>
	Dewar	Petitioner	3.9542	3
	Spring Oaks	Petitioner	2.0417	2
	DeLeon’s	Petitioner	1.9083	1
Northwest	<b>Hackney</b>	<b>Winner</b>	<b>3.6875</b>	<b>4</b>
	Tree King	Petitioner	1.3583	1
Northeast	<b>San Felasco</b>	<b>Winner</b>	<b>3.9750</b>	<b>5</b>
	Bill’s	Petitioner	1.2250	1
Southwest	<b>Alpha</b>	<b>Winner</b>	<b>4.1042</b>	<b>5</b>
	Perkins	Petitioner	2.1167	1
	TropiFlora	Petitioner	Rejected; not scored	
Southeast	<b>Costa</b>	<b>Winner</b>	<b>4.4000</b>	<b>5</b>
	Bill’s	Petitioner	1.5500	1

Significantly, the Final Scorecard was included in the legislative record (including staff analyses) as the bill that was adopted as the 2017 Law (Senate Bill 8-A) moved through the various legislative committees. *See, e.g.*, Ex. A. This fact shows that the legislature was validating and intended to utilize the Final Ranks and other scores set forth in the Final Scorecard. When enacting the One-Point Provision, the legislature knew what the Final Ranks were and knew how many 2015 DO applicants were within one point of the highest-ranking applicant in their regions.

**As an executive-branch agency, DOAH lacks power to rule on the constitutionality of a statute.**

Petitioners also argue that the Department's interpretation of the One-Point Provision would render that provision an unconstitutional special law and therefore DOAH may not adopt that interpretation. Petitioners invite error. DOAH—as an executive branch agency—lacks jurisdiction to make determinations regarding the facial constitutionality of a statute. *See, e.g., Butler v. State, Dep't of Ins.*, 680 So. 2d 1103, 1107 (Fla. 1st DCA 1996). DOAH is not a court or arm of the judicial branch. And if DOAH were to reject the Department's interpretation on the basis that the interpretation would render the One-Point Provision unconstitutional, DOAH would be doing exactly that: making a determination regarding the facial constitutionality of a statute. In other words, DOAH would be acting outside its jurisdiction.

Ultimately, the One-Point Provision's plain language must be applied to deny the petitions and requests for licensure.

**These matters must be consolidated and set for final hearing now.**

In the context of the Department's request for consolidation, the number of available licenses cannot be determined outside of a recommended order from which exceptions may be taken by the parties. If the Petitioners do not want an *Ashbacher* hearing, the Department will not at this time insist that one is required. Because the Department contends that none of the petitioners

is qualified, the Department is willing to proceed immediately to a hearing that will not involve comparative review among Petitioners.

Still, and without regard to the number of available licenses, the matters should be consolidated. Seven petitioners will want to take depositions of an agency representative and an agency representative will likely be required to testify *seven times* on the same facts and issues. There is frankly little to nothing unique about each petition. The potential burden on the State's witness outweighs the little, if any, impact on Petitioners. The number of available licenses is, today, immaterial to consolidation. The number of available licenses is, at this point, immaterial to consolidation that will not involve an *Ashbacker* comparative review.<sup>5</sup> Therefore, the matters should be consolidated for discovery and trial; however, the ALJ should issue separate recommended orders for consideration by the Department in issuing its final orders on each petition.

#### **CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing was served on September 24, 2018, by email to:

Daniel R. Russell  
William Dean Hall, III  
Jones Walker LLP  
215 South Monroe Street, Suite 130  
Tallahassee, Florida 32301  
drussell@joneswalker.com  
whall@joneswalker.com  
mharrell@joneswalker.com

*Counsel for Petitioner Dewar Nurseries, Inc.*

/s/ Eduardo S. Lombard  
Eduardo S. Lombard  
Florida Bar No. 0153590  
Megan S. Reynolds

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<sup>5</sup> If it is determined at a later date that an *Ashbacker* review is necessary, it can be addressed at that time.

Florida Bar No. 0042000

Vezina, Lawrence & Piscitelli, P.A.  
413 East Park Avenue  
Tallahassee, Florida 32301  
(850) 224-6205  
elombard@vlplaw.com  
mreynolds@vlplaw.com  
rhodge@vlplaw.com

*Counsel for Respondent Florida Department  
of Health*

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Appropriations

BILL: SB 8-A

INTRODUCER: Senators Bradley and Young

SUBJECT: Medical Use of Marijuana

DATE: June 8, 2017                      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	<b>Fav/3 amendments</b>
2.	<u>Loe</u>	<u>Hansen</u>	<u>AP</u>	<b>Favorable</b>

**Please see Section IX. for Additional Information:**

AMENDMENTS - Significant amendments were recommended

**I. Summary:**

SB 8-A implements the provisions of s. 29, Art. X, of the State Constitution. The bill:

- Exempts the sale of marijuana and marijuana delivery devices from sales tax.
- Establishes procedures for physicians to issue physician certifications to patients who have qualifying medical conditions.
- Establishes residency requirements for patients to be issued a Medical Marijuana Use Registry Identification Card (ID card).
- Establishes qualifications required to become a caregiver including requiring the Department of Health (DOH) to create a caregiver certification course that each caregiver must take.
- Limits the number of caregivers each patient may have and the number of patients each caregiver may assist.
- Changes the name of the Compassionate Use Registry to the Medical Marijuana Use Registry and requires the DOH to issue ID cards to patients and caregivers.
- Details requirements for MMTC applicants and standards that each MMTC must meet to maintain licensure.
- Grandfathers in existing dispensing organizations as MMTCs and requires the DOH to license 10 new MMTCs by October 3, 2017, and then four new MMTCs each time the registry increases by 100,000 registered patients.
- Limits the number of dispensing facilities each MMTC may operate to 25 statewide and per region based on the percentage of population in each region. The total number of dispensing facilities each MMTC may operate increases by five per 100,000 patients registered in the Medical Marijuana Use Registry. MMTCs may sell dispensing facility slots to each other. These caps expire on April 1, 2020.



- Requires laboratory testing of MMTC products and creates a certification program for medical marijuana testing laboratories.
  - Preempts the regulation of cultivation and processing of marijuana to the state.
  - Allows local governments to ban MMTC dispensing facilities. If a local government does not ban dispensing facilities it may not place any restrictions on the number of dispensing facilities allowed and may not adopt any regulations for dispensing facilities that are more restrictive than its ordinances regulating pharmacies.
  - Requires the DOH and the Department of Highway Safety and Motor Vehicles (DHSMV) to establish educational campaigns related to the medical use of marijuana.
  - Creates the Coalition for Medicinal Cannabis Research and Education (coalition) to conduct rigorous scientific research, provide education, disseminate research, and to guide policy development for the adoption of a statewide policy on ordering and dosing practices for the medicinal use of cannabis.
  - Includes rulemaking and other provisions to aid the DOH in adopting rules and implementing the provisions of Amendment 2 within the time frame specified in the amendment.
- Includes appropriations for the state 2017-2018 fiscal year for the DOH, for the education programs, and for the Coalition.

## II. Present Situation:

### Treatment of Marijuana in Florida

Florida law defines cannabis as “all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin,”<sup>1</sup> and places it, along with other sources of tetrahydrocannabinol (THC), on the list of Schedule I controlled substances.<sup>2</sup> The definition excludes “low-THC cannabis” as defined in s. 381.986, F.S., if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed in conformance with that section.

Schedule I controlled substances are substances that have a high potential for abuse and no currently accepted medical use in the United States.<sup>3</sup> As a Schedule I controlled substance, possession and trafficking of cannabis carry criminal penalties that vary from a first-degree misdemeanor<sup>4</sup> up to a first-degree felony with a mandatory minimum sentence of 15 years in state prison and a \$200,000 fine.<sup>5</sup> Paraphernalia<sup>6</sup> that is sold, manufactured, used, or possessed with the intent to be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance, is also

<sup>1</sup> Section 893.02(3), F.S.

<sup>2</sup> Section 893.03(1)(c)7. and 37., F.S.

<sup>3</sup> Section 893.03(1), F.S.

<sup>4</sup> This penalty is applicable to possession or delivery of less than 20 grams of cannabis. *See* s. 893.13(3) and (6)(b), F.S.

<sup>5</sup> Trafficking in more than 25 pounds, or 300 plants, of cannabis is a first-degree felony with a mandatory minimum sentence that varies from three to 15 years in state prison depending on the quantity of the cannabis possessed, sold, etc. *See* s. 893.135(1)(a), F.S.

<sup>6</sup> Section 893.145, F.S.

prohibited and carries criminal penalties ranging from a first degree misdemeanor to a third degree felony.<sup>7</sup>

## **Medical Marijuana in Florida: the Compassionate Medical Cannabis Act of 2014**

### ***Patient Treatment with Low-THC Cannabis***

The Compassionate Medical Cannabis Act of 2014<sup>8</sup> (act) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)<sup>9</sup> for medical use<sup>10</sup> by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. The act provides that a Florida licensed allopathic or osteopathic physician who has completed the required training<sup>11</sup> and has examined and is treating such a patient may order low-THC cannabis for that patient to treat such disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for that patient. In order for a physician to order low-THC cannabis for a patient, all of the following conditions must apply:

- The patient is a permanent resident of Florida;
- The physician has treated the patient for at least 3 months immediately preceding the patient's registration and has determined that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient;<sup>12</sup>
- The physician registers as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the DOH and updates the registry to reflect the contents of the order;
- The physician maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis;
- The physician submits the patient treatment plan quarterly to the University of Florida, College of Pharmacy (UFCP) for research on the safety and efficacy of low-THC cannabis on patients; and
- The physician obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community about the effectiveness of treatment of the patient's

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<sup>7</sup> Section 893.147, F.S.

<sup>8</sup> Chapter 2014-157, Laws of Fla., codified in s. 381.986, F.S.

<sup>9</sup> Section 381.986(b), F.S., defines "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

<sup>10</sup> Section 381.986(1)(c), F.S., defines "medical use" as administration of the ordered amount of low-THC cannabis; and the term does not include the possession, use, or administration by smoking, or the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative. Section 381.986(1)(e), F.S., defines "smoking" as burning or igniting a substance and inhaling the smoke; smoking does not include the use of a vaporizer.

<sup>11</sup> Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing.

<sup>12</sup> If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record.

condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects.<sup>13</sup>

The act creates exceptions to existing law to allow qualified patients<sup>14</sup> and their legal representatives to purchase, acquire, and possess low-THC cannabis – up to the amount ordered – for that patient’s medical use; and to allow dispensing organizations (DO) and their owners, managers, and employees to acquire, possess, cultivate, and dispose of excess product in reasonable quantities to produce low-THC cannabis and to possess, process, and dispense low-THC cannabis. The DOs and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.<sup>15</sup>

### ***Patient Treatment with Medical Cannabis***

Chapter 2016-123, Laws of Florida, amended the act to expand the regulatory structure relating to dispensing low-THC cannabis and authorized approved dispensing organizations to cultivate and dispense medical cannabis to eligible patients as defined under the Right to Try Act (RTTA).<sup>16</sup> In conjunction with s. 381.986, F.S., the RTTA allows physicians to treat eligible patients with terminal conditions with medical cannabis by including medical cannabis<sup>17</sup> within the definition of an investigational drug, biological product, or device. Physicians must order the use of medical cannabis for those patients pursuant to the provisions of s. 381.986, F.S.

### ***Dispensing Organizations under the Act***

Section 381.986, F.S., requires that the DOH approve five DOs, one in each of five regions throughout the state. In order to be approved as a DO, an applicant must possess a certificate of registration issued by the Department of Agriculture and Consumer Services (DACS) for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operating as a registered nursery in this state for at least 30 continuous years. DOs must be vertically integrated, meaning the DO performs all stages in the production, processing, marketing, and retailing of low-THC and medical cannabis. Applicants are required to demonstrate:

- The technical and technological ability to cultivate and produce low-THC cannabis;
- The ability to secure the premises, resources, and personnel necessary to operate as a DO;
- The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances;
- An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the DOH;
- The financial ability to maintain operations for the duration of the two year approval cycle, including the provision of certified financials to the DOH;
- That all owners and managers have been fingerprinted and have successfully passed a Level 2 background screening pursuant to s. 435.04, F.S; and

<sup>13</sup> Section 381.986(2), F.S.

<sup>14</sup> Section 381.986(1)(d), F.S., defines a “qualified patient” as a Florida resident who has been added by a physician licensed under ch. 458 or 459, F.S., to the compassionate use registry to receive low-THC cannabis from a DO.

<sup>15</sup> Section 381.986(7), F.S.

<sup>16</sup> Section 499.0295, F.S.

<sup>17</sup> “Medical cannabis” means all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, sale, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a DO for medical use by an eligible patient as defined in the Right to Try Act.

- The employment of a medical director, who must be a physician<sup>18</sup> and successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis.<sup>19</sup>

An approved DO must post a \$5 million performance bond within 10 business days of approval. The DOH is authorized to charge an initial application fee and a licensure renewal fee, but is not authorized to charge an initial licensure fee.<sup>20</sup> An approved DO must maintain all approval criteria at all times.<sup>21</sup>

Beginning on July 7, 2014, the DOH held several rule workshops<sup>22</sup> to write and adopt rules implementing the provisions of s. 381.986, F.S., and the DOH put forward a proposed rule on September 9, 2014.<sup>23</sup> This proposed rule was challenged by multiple organizations involved in the rulemaking workshops and was found to be an invalid exercise of delegated legislative authority by an administrative law judge on November 14, 2014.<sup>24</sup> Afterward, the DOH held a negotiated rulemaking workshop in February of 2015, which resulted in a new proposed rule being published on February 6, 2015.<sup>25</sup> The new proposed rule was also challenged on, among other things, the DOH's statement of estimated regulatory costs and the DOH's conclusion that the rule will not require legislative ratification. Hearings were held on April 23 and 24, 2015, and a final order was issued on May 27, 2015, which found the rule to be valid.<sup>26</sup> The rule took effect June 17, 2015, and the DOH held an application period for DO approval, which ended on July 8, 2015. Twenty-eight applications were submitted and 26 of the applications were scored.<sup>27</sup>

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<sup>18</sup> Licensed under ch. 458 or 459, F.S.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> Section 381.986(6), F.S.

<sup>22</sup> Audio recordings of the rule development workshops are available on the DOH website at: <http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/rulemaking/index.html> (last visited June 7, 2017).

<sup>23</sup> Proposed Rule ch. 64-4, F.A.C., ID 14941024, (Aug. 14, 2014) and changed, ID 15040352, (Sept. 9, 2014).

<sup>24</sup> Tornello Landscape Corp. v. DOH, Case No. 14-4547RP; Fl. Medical Cannabis Assoc. v. DOH, Case No. 14-4517RP; Plants of Ruskin, Inc. v. DOH, Case No. 14-4299RP; Costa Farms, LLC v. DOH, Case No. 14-4296RP (Fla. DOAH 2014). A copy of each Final Order is available on the Division of Administrative Hearings website.

<sup>25</sup> Proposed Rule ch. 64-4, F.A.C., ID 15645147, (Feb. 2, 2015).

<sup>26</sup> Baywood Nurseries Co., Inc. v. DOH, Case No. 15-1694RP (Fla. DOAH 2015).

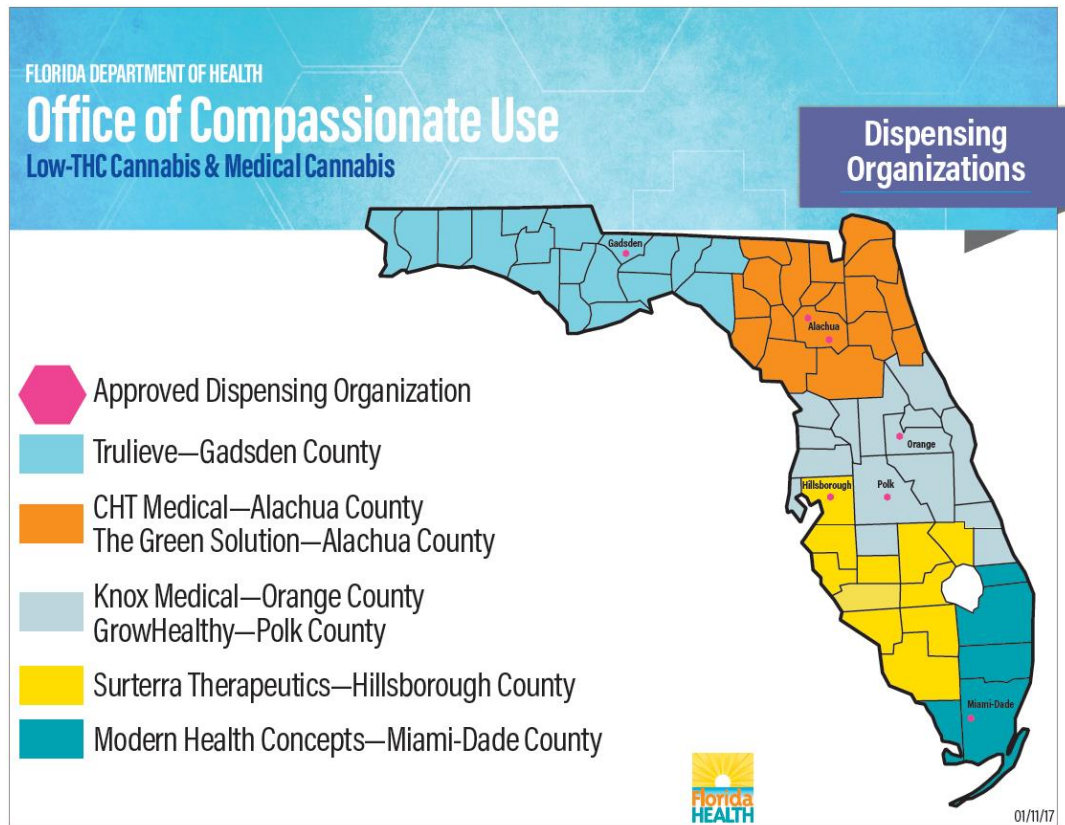
<sup>27</sup> Information about the applications and the approved DOs is available on the DOH, Office of Compassionate Use, website, available at: <http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/dispensing-organizations/dispensing-application-process/index.html> (last visited June 7, 2017).

Applicant	Region	Reviewer 1	Reviewer 2	Reviewer 3	Final Rank	Regional Rank
3 Boys	Southwest	2.6875	3.1000	4.6125	3.4667	4
Alpha	Southwest	4.8750	3.5000	3.9375	4.1042	5
Perkins	Southwest	1.3750	2.0375	2.9375	2.1167	1
Plants of Ruskin	Southwest	2.7625	2.3375	2.8375	2.6458	2
Sun Bulb	Southwest	3.3000	4.0250	2.1500	3.1583	3
Bill's	Southeast	2.1125	1.1500	1.3875	1.5500	1
Costa	Southeast	4.2750	4.2375	4.6875	4.4000	5
Keith's St. Germain	Southeast	2.4125	4.1250	3.1000	3.2125	4
Nature's Way	Southeast	2.4500	3.4875	2.7125	2.8833	2
Redland	Southeast	3.7500	2.0000	3.7750	3.1750	3
Deleon	Central	1.8375	2.8875	1.0000	1.9083	1
Dewar	Central	4.7500	4.5750	2.5375	3.9542	3
Knox	Central	4.1750	6.5875	5.8750	5.5458	7
McCrorry's	Central	5.4125	4.6875	6.5250	5.5417	6
Redland	Central	6.4000	2.3375	4.5500	4.4292	4
Spring Oak	Central	1.4375	1.3750	3.3125	2.0417	2
Treadwell	Central	3.9875	5.4375	4.2750	4.5667	5
Bill's	Northeast	1.2500	1.4250	1.0000	1.2250	1
Chestnut Hill	Northeast	4.7250	3.6500	3.0000	3.7917	4
Hart's	Northeast	3.2375	2.0750	2.0000	2.4375	2
Loop's	Northeast	2.7250	3.9875	4.0000	3.5708	3
San Felasco	Northeast	3.0625	3.8625	5.0000	3.9750	5
Alpha	Northwest	3.3125	2.9000	2.0000	2.7375	3
Hackney	Northwest	3.6125	3.4500	4.0000	3.6875	4
Hart's	Northwest	1.7250	1.9250	3.0000	2.2167	2
Tree King	Northwest	1.3500	1.7250	1.0000	1.3583	1

On November 23, 2015, the DOH approved a DO in each of the following five regions as required by the act: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.<sup>28</sup> Numerous petitions were filed challenging the DOH’s selection process. In order to allow the approved DOs to begin dispensing products, the 2016 Legislature required the DOH to approve as a DO applicants that received the highest aggregate score through the DOH’s evaluation process, notwithstanding any prior determination by the DOH that the applicant failed to meet the requirements of s. 381.986, F.S. The Legislature also provided that if the Division of Administrative Hearings, the DOH, or a court of competent jurisdiction makes a final determination that an applicant was entitled to be a DO, that both this DO and currently approved DOs may operate in the same region.<sup>29</sup> Currently, in addition to the five DOs originally approved, the DOH has since approved The Green Solution in Alachua County and Grow Health in Polk County. The following map depicts the currently approved DOs.

<sup>28</sup> Section 381.986(5)(b), F.S. A map of the dispensing regions and approved dispensing organizations is available on the DOH website at: <http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/documents/ocu-dispensing-map.pdf> (last visited June 7, 2017).

<sup>29</sup> Chapter 2016-123, Laws of Fla.



In addition to the currently approved DOs, s. 381.986(5)(c), F.S., requires the DOH to approve three additional DOs upon the registration of 250,000 active qualified patients in the compassionate use registry. At least one of the newly approved DOs must be an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association. These additional applicants are not required to meet the requirement to possess a certificate of registration issued by the DACS for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operating as a registered nursery in Florida for at least 30 continuous years.

***The Compassionate Use Registry***

The act requires the DOH to create a secure, electronic, and online registry for the registration of physicians and patients and for the verification of patient orders by DOs, which is accessible to law enforcement.<sup>30</sup> The registry must allow DOs to record the dispensing of low-THC cannabis, and must prevent an active registration of a patient by multiple physicians. Physicians must register qualified patients with the registry and DOs are required to verify that the patient has an active registration in the registry, that the order presented matches the order contents as recorded in the registry, and that the order has not already been filled before dispensing any low-THC cannabis. The DOs are also required to record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.<sup>31</sup> The Compassionate Use Registry became operational on

<sup>30</sup> Section 381.986(5)(a), F.S.

<sup>31</sup> Section 381.986(6), F.S.

July 11, 2016.<sup>32</sup> As of June 1 2017, there were 15,878 patients registered with the Compassionate Use Registry.<sup>33</sup>

### ***The Office of Compassionate Use and Research on Low-THC Cannabis***

The DOH was required to establish the Office of Compassionate Use under the direction of the deputy state health officer to administer the act.<sup>34,35</sup>

The act includes several provisions related to research on low-THC cannabis and cannabidiol including:

- Requiring physicians to submit quarterly patient treatment plans to the UFCP for research on the safety and efficacy of low-THC cannabis;<sup>36</sup>
- Authorizing state universities to perform research on cannabidiol and low-THC cannabis and exempting them from the provisions in ch. 893, F.S., for the purposes of such research;<sup>37</sup> and
- Appropriating \$1 million to the James and Esther King Biomedical Research Program for research on cannabidiol and its effects on intractable childhood epilepsy.<sup>38</sup>

### **Medical Marijuana in Florida: Amendment 2 (2016)**

On November 4, 2016, Amendment 2 was voted into law and established Article X, section 29 of the State Constitution. This section of the constitution became effective on January 3, 2017, and creates several exemptions from criminal and civil liability for:

- Qualifying patients medically using marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- Medical Marijuana Treatment Centers (MMTCs), their agents, and employees for actions or conduct under the amendment and in compliance with DOH rules.

The constitution defines multiple terms including:

- “Qualifying patient” to mean a person who:
  - Has been diagnosed with a “debilitating medical condition;”

<sup>32</sup> Office of Compassionate Use, *Implementation Timeline* (October 2016) available at [http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/\\_documents/ocu-timeline.pdf](http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/_documents/ocu-timeline.pdf), (last visited June 7, 2017).

<sup>33</sup> Email from the Legislative Affairs Director, Department of Health (June 1, 2017) (n file with the Senate Committee on Health Policy).

<sup>34</sup> Section 385.212, F.S.

<sup>35</sup> The Office of Compassionate Use is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies by: creating a network of state universities and medical centers recognized for demonstrating excellence in patient-centered coordinated care for persons undergoing cancer treatment and therapy in this state; making any necessary application to the U.S. Food and Drug Administration (FDA) or a pharmaceutical manufacturer to facilitate enhanced access to compassionate use for Florida patients; and entering into agreements necessary to facilitate enhanced access to compassionate use for Florida patients. *See* ss. 381.925 and 385.212, F.S.

<sup>36</sup> Section 381.986(2)(e), F.S.

<sup>37</sup> Section 385.211, F.S.

<sup>38</sup> Chapter 2014-157, Laws of Fla. The DOH and the University of Florida executed a contract (ID 5EP01) on June 5, 2015, and \$483,334 of the \$1 million grant award has been spent. Florida Accountability Contract Tracking System (FACTS) available at: <https://facts.fldfs.com/Search/ContractDetail.aspx?AgencyId=640000&ContractId=5EP01>. (last visited June 7, 2017).

- Has a “physician certification;” and
- Has a valid qualifying patient identification card issued by the DOH.
- In the case of a minor patient, must also have the consent of a parent or legal guardian prior to both obtaining a physician certification and obtaining an identification card from the DOH.<sup>39</sup>
- “Debilitating Medical Condition” to mean:
  - Cancer;
  - Epilepsy;
  - Glaucoma;
  - HIV/AIDS;
  - Post-Traumatic Stress Disorder (PTSD);
  - Amyotrophic lateral sclerosis (ALS);
  - Crohn’s Disease;
  - Parkinson’s Disease;
  - Multiple Sclerosis; or
  - Another debilitating medical condition of the same kind or class as, or comparable to, the enumerated conditions.
  - Additionally, a physician must believe that the medical use of marijuana would likely outweigh the potential health risks for the patient.
- “Marijuana” to have the meaning given to cannabis in section 893.02(3), F.S. (2014), and, in addition, “low-THC cannabis” as defined in section 381.986(1)(b), F.S. (2014), shall also be included in the meaning of the term “marijuana.”
- “MMTC” or “MTC” to mean an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers and is registered by the DOH.
- “Medical use” to mean the acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with DOH rules, or of related supplies by a qualifying patient or caregiver for use by the caregiver’s designated qualifying patient for the treatment of a debilitating medical condition.
- “Physician Certification” to mean a written document signed by a person who is “licensed to practice medicine” in Florida stating:
  - The physician has conducted a medical examination of the patient and a full assessment of the patient’s medical history;
  - That, in the physician’s professional opinion, the patient has a debilitating medical condition;
  - That, in the physician’s professional opinion, the medical use of marijuana will outweigh the health risks for the patient; and
  - For how long the physician recommends the medical use of marijuana for the patient.

Once certified, a patient may designate one or more caregivers to assist him or her with the medical use of marijuana. The amendment defines a “caregiver” as a person who is at least 21 years of age who has agreed to assist with a qualifying patient’s medical use of marijuana and has qualified for and obtained a caregiver identification card issued by the DOH. Caregivers:

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<sup>39</sup> This provision is included in the definition of “physician certification.”



- Are prohibited from consuming medical marijuana;
- Must obtain an ID card from the DOH;
- Are subject to standards and qualifications established by the DOH including:
  - Background checks;
  - Procedures for issuing ID cards; and
  - Limitations on the number of caregivers per patient and the number of patients per caregiver.

The DOH is required to register MMTCs that will be authorized to acquire, cultivate, possess, process, transfer, transport, sell, distribute, dispense, or administer medical marijuana, related supplies, or educational materials to patients and caregivers. The DOH is required to adopt rules regarding MMTCs including:

- Procedures to register as an MMTC;
- Procedures for the issuance, renewal, suspension, and revocation of MMTC registrations; and
- Standards to ensure proper security, record keeping, testing, labeling, inspection, and safety.

The amendment requires the DOH to adopt rules no later than July 3, 2017, six months after its effective date. The stated purpose of the rules is to ensure the availability and safe use of medical marijuana by qualifying patients. Currently, the DOH has begun the rulemaking process to implement Article X, section 29 of the State Constitution and has held several workshops around Florida.<sup>40</sup> The DOH is required to adopt rules for:

- Issuing patient and caregiver ID cards;<sup>41</sup>
- Procedures for establishing caregiver qualifications;
- Procedures for registering MMTCs; and
- A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply, based on the best available medical evidence. This presumption can be overcome on an individual patient basis.

If the DOH does not adopt rules by the deadline, the amendment creates a cause of action for any Florida citizen to seek judicial relief to compel the DOH's compliance.

Additionally, the DOH is required to begin registering MMTCs and issuing patient and caregiver ID cards by October 3, 2017, nine months after the amendment's effective date. If the DOH does not comply with this requirement, the amendment states that a physician certification is sufficient for a person to become a qualifying patient without being issued an ID card from the DOH.

The amendment also creates a number of specific restrictions on its exemption from liability, and its grants of authority, including specifically:

- Not repealing or allowing violations of other laws related to the non-medical use of marijuana;

<sup>40</sup> Rule 64-4.012, F.A.C., rule notice published on Jan. 17, 2017, *available at* <https://www.flrules.org/gateway/ruleNo.asp?id=64-4.012>, (last visited on June 7, 2017).

<sup>41</sup> On Feb. 18, 2017, the DOH adopted Rule 64-4.011, F.A.C., addressing the issuance of Compassionate Use Registry Identification Cards. This rule may bring the DOH into compliance with the requirement to adopt rules for issuing ID cards by July 3, 2017; however, the rule may need requiring amending to comply with constitutional terms and to comply with changes to s. 381.986, F.S., provided in this bill.

- Not permitting the operation of any vehicle under the influence of marijuana;
- Not requiring the accommodation of the use of marijuana in specific areas or in any public place;
- Not requiring any health insurance provider to cover the medical use of marijuana; and
- Not affecting laws related to negligence or malpractice on the part of any patient, caregiver, physician, or MMTC agent or employee.

The State Constitution authorizes the Legislature to enact laws consistent with the constitution's language, and provides for severability so that if any clause, sentence, paragraph or section of the amendment, or an application thereof, is found to be invalid by a court of competent jurisdiction, other provisions shall continue to be in effect to the fullest extent possible.

The Revenue Estimating Conference has estimated that under Amendment 2 and the proposed DOH rules, sales tax revenue from medical marijuana sales will be \$2.6 million in Fiscal Year 2017-2018 and will increase to \$24.3 million in Fiscal Year 2021-2022.

### **Medical Marijuana in Florida: The Necessity Defense**

Despite the fact that the use, possession, and sale of marijuana are prohibited by state law, Florida courts have found that circumstances can necessitate medical use of marijuana and circumvent the application of criminal penalties. The necessity defense was successfully applied in a marijuana possession case in *Jenks v. State* where the First District Court of Appeal found that s. 893.03, F.S., does not preclude the defense of medical necessity for the use of marijuana if the defendant:

- Did not intentionally bring about the circumstance which precipitated the unlawful act;
- Could not accomplish the same objective using a less offensive alternative available; and
- The evil sought to be avoided was more heinous than the unlawful act.<sup>42</sup>

In the cited case, the defendants, a married couple, were suffering from uncontrollable nausea due to AIDS treatment and had testimony from their physician that he could find no effective alternative treatment. Under these facts, the court found that the defendants met the criteria to qualify for the necessity defense and ordered an acquittal of the charges of cultivating cannabis and possession of drug paraphernalia.

### **Medical Marijuana Laws in Other States**

Currently, 28 states, the District of Columbia, and Guam have some form of law that permits the use of marijuana for medicinal purposes.<sup>43</sup> These laws vary widely in detail but most share

<sup>42</sup> *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *review denied*, 589 So.2d 292 (Fla. 1991).

<sup>43</sup> These states include: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and New York was the most recent state to pass medical marijuana legislation in June 2014. Seventeen states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol). Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. National Conference of State Legislatures, *State Medical Marijuana Laws*, (Mar. 16, 2017), available at <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx> (last visited June 7, 2017).

certain features. For example, most state laws require an identification card and registry for patients and caregivers to use medical marijuana; require the patient to receive certification from up to two physicians that the patient has a qualifying condition before the patient may use medical marijuana; allow a patient to designate a caregiver who can possess the medical marijuana and assist the patient in using the medical marijuana; and provide general restrictions on how medical marijuana can be obtained (self-cultivated or from a dispensary) and where it can be used.<sup>44</sup>

Of the 17 states with low-THC cannabis laws similar to s. 381.986, F.S., most specify that the use of such low-THC cannabis is reserved for patients with epileptic or seizure disorders. Florida allows the treatment of cancer and Georgia allows the treatment of end stage cancer and other specified conditions. Additionally, the definition of low-THC cannabis differs from state to state. The THC level allowed ranges from a high of below five percent to less than 0.3 percent; most states restrict the level of THC to below one percent. CBD levels are generally required to be high, with most states requiring at least 10 percent.<sup>45</sup>

### ***Interaction with the Federal Government***

The federal Controlled Substances Act lists marijuana as a Schedule 1 drug and provides no exceptions for medical uses.<sup>46</sup> Possession, manufacture, and distribution of marijuana is a crime under federal law.<sup>47</sup> Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under state law, state medical marijuana laws, or Constitutional provisions, do not protect individuals from prosecution under federal law.

In 2013, the U.S. Department of Justice (USDOJ) issued statements indicating that the federal government would not pursue cases for low-level drug crimes, leaving such prosecutions largely up to state authorities. The U.S. Attorney General issued a statement that the USDOJ was changing policy such that individuals “who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels, will no longer be charged with offenses that impose draconian mandatory minimum sentences... [and] would instead receive sentences better suited to their individual conduct...”<sup>48</sup> Further, the USDOJ issued a memorandum clarifying that the department considers small-scale marijuana use to be a state matter which states may choose to punish, and certain operations adhering to state laws legalizing marijuana in conjunction with robust state regulatory systems would be far less likely to come under federal scrutiny.<sup>49</sup> In addition, a rider in recent appropriations acts and continuing resolutions has prohibited the USDOJ from using appropriated funds to prevent specified states

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<sup>44</sup> Analysis by Senate Health Policy committee staff of *supra* note 49.

<sup>45</sup> *Supra* note 49.

<sup>46</sup> 21 U.S.C. s. 812. Note: On August 11, 2016, the Federal Drug Enforcement Administration refused two petitions to reschedule marijuana under the Controlled Substances Act, see <https://www.dea.gov/divisions/hq/2016/hq081116.shtml>, (last visited on June 7, 2017).

<sup>47</sup> The punishments vary depending on the amount of marijuana and the intent with which the marijuana is possessed. See 21 U.S.C ss. 841-865.

<sup>48</sup> USDOJ, *Smart on Crime: Reforming the Criminal Justice System for the 21<sup>st</sup> Century*, (Aug. 2013), p. 3, available at <http://www.justice.gov/ag/smart-on-crime.pdf> (last visited on June 7, 2017).

<sup>49</sup> USDOJ Memorandum for all U.S. Attorneys from James M. Cole, Deputy Attorney General, *Guidance Regarding Marijuana Enforcement* (August 29, 2013), available at <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf> (last visited June 7, 2017).

(including Florida) from implementing the states' own medical marijuana laws.<sup>50</sup> It is worth noting that, with the election of President Trump and changes to the leadership of the USDOJ, the guidance issued by the USDOJ may be amended in the future; however, it would require an act of Congress to amend the rider preventing the USDOJ from using funds to prevent specified states from implementing medical marijuana laws.

### III. Effect of Proposed Changes:

**Section 1** creates a new unnumbered section of the Florida Statutes which establishes the legislative intent to implement s. 29, Art. X of the State Constitution by creating a unified regulatory structure. The section establishes that the act will expire six months after the effective date of any constitutional amendment related to cannabis or marijuana.

**Section 2** amends s. 212.08, F.S., to exempt the sales of marijuana and marijuana delivery devices from taxation.

**Section 3** amends s. 381.986, F.S., to implement the provisions of s. 29, Art. X of the State Constitution. The bill substantially rewords the section, the details of the new provisions are as follows.

#### Definitions

The bill defines the terms:

- “Caregiver” to mean a resident of the state who has agreed to assist with a qualified patient’s medical use of marijuana, has a caregiver identification card, and meets the requirements for caregivers established in the section.
- “Chronic nonmalignant pain” to mean pain that is caused by a qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course of that qualifying medical condition.
- “Close relative” to mean a spouse, parent, sibling, grandparent, child, or grandchild, whether related by whole or half blood, by marriage, or by adoption.
- “Edibles” to mean commercially produced food items made with marijuana oil, but no other form of marijuana, that are produced and dispensed by a MMTC.
- “Marijuana” to mean all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin, including low-THC cannabis, which are dispensed from a MMTC for medical use by a qualified patient.
- “Marijuana testing laboratory” to mean a facility that collects and analyzes marijuana samples from a MMTC and has been certified by the department pursuant to s. 381.988, F.S.

<sup>50</sup> See Pub. Law No. 114-113, s. 542 (Consolidated Appropriations Act, 2016). A recent court order by the U.S. District Court for the Northern District of California recently held that a similar provision in the previous appropriations act (s. 538, Pub. L. No. 113-235) does not prohibit the USDOJ from enforcing violations of *federal* marijuana laws by individuals or businesses who are complying with state medical marijuana laws. *U.S. v. Marin Alliance for Medical Marijuana and Shaw*, Order re: Motion to Dissolve Permanent Injunction, No. C 98-00086 CB, (Oct. 19, 2015), *available at* <http://www.scribd.com/doc/286089509/US-vs-Marine-Alliance-for-Medical-Marijuana#scribd> (last visited June 7, 2017).

- “Medical use” to mean the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. The term does not include:
  - Possession, use, or administration of marijuana that was not purchased or acquired from a MMTC.
  - Possession, use, or administration of marijuana in a form for smoking, in the form of commercially produced food items other than edibles, or of marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping.
  - Use or administration of any form or amount of marijuana in a manner that is inconsistent with the qualified physician’s directions or physician certification.
  - Transfer of marijuana to a person other than the qualified patient for whom it was authorized or the qualified patient’s caregiver on behalf of the qualified patient.
  - Use or administration of marijuana in the following locations:
    - On any form of public transportation, except for low-THC cannabis.
    - In any public place, except for low-THC cannabis.
    - In a qualified patient’s place of employment, except when permitted by his or her employer.
    - In a state correctional institution, as defined in s. 944.02, F.S., or a correctional institution, as defined in s. 944.241, F.S.
    - On the grounds of a preschool, primary school, or secondary school, except as provided in s. 1006.062, F.S.
    - In a school bus, a vehicle, an aircraft, or a motorboat, except for low-THC cannabis.
- “Qualified physician” to mean a person who holds an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and is in compliance with the physician education requirements.
- “Terminal condition” to mean a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

## **Patient and Physician Requirements**

### ***Qualifying Medical Conditions***

The bill specifies that the following medical conditions qualify a patient to receive marijuana and a marijuana delivery device: cancer, epilepsy, glaucoma, positive status for HIV, AIDS, PTSD, ALS, Crohn’s disease, Parkinson’s disease, multiple sclerosis, medical conditions of the same kind or class as the preceding, a terminal condition,<sup>51</sup> and chronic nonmalignant pain. Other than terminal conditions, this list is identical to the list of debilitating medical conditions in s. 29, Art. X of the State Constitution.

### ***Physician and Medical Director Training***

In order to issue physician certifications or to be a medical director of an MMTC, the bill requires that a physician complete a 2-hour training course prior to being approved to issue physician certifications and at each licensure renewal. The course must encompass the requirements of the section and any rules adopted to implement the section. The bill requires the

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<sup>51</sup> The terminal condition must be diagnosed by a physician other than the certifying physician.

Florida Medical Association (FMA) or the Florida Osteopathic Medical Association (FOMA) to develop and offer the course annually. The FMA or FOMA may not charge more than \$500 to take the course and may offer the course in a distance learning format, including online.

### ***Restrictions on Issuing Physician Certifications***

A physician may not issue a physician certification if he or she is employed by, or has any direct or indirect economic interest in, an MMTC or marijuana testing laboratory.

### ***Procedures for Issuing a Physician Certification***

Prior to issuing a physician certification to a patient, a physician must:

- Conduct an in-person physical examination of the patient and a full assessment of the patient's medical history;
- Diagnose the patient with at least one qualifying medical condition;
- Determine that the patient's use of marijuana would outweigh the risks;
  - If the patient is under the age of 18, two physicians must make this determination;
- Determine whether the patient is pregnant;
  - Physicians may only certify pregnant patients for low-THC cannabis;
- Review the patient's controlled substance prescription history in the prescription drug monitoring program database;
- Review the medical marijuana use registry (registry) to determine that the patient does not have an active physician certification from another qualified physician; and
- Register as the issuer of the physician certification on the registry. The physician must also:
  - Enter the contents of the physician certification into the registry including the patient's qualifying condition, the dosage not to exceed the daily dose amount determined by the DOH, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient;
  - Update the registry if any change is made to the physician certification; and
  - Deactivate the patient's registration when the physician no longer recommends the patient medically use marijuana.

### ***Informed Consent***

In addition to the criteria detailed above, a physician must also obtain the patient's voluntary and written informed consent each time he or she issues the patient a physician certification. The physician must use a standardized form created by the Board of Medicine (BOM) or the Board of Osteopathic Medicine (BOOM) and, if the patient is a minor, the physician must also obtain the consent of the patient's parent or legal guardian. The standardized informed consent form must include information related to:

- The Federal Government's classification of marijuana as a Schedule I controlled substance.
- The approval and oversight status of marijuana by the Food and Drug Administration.
- The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.
- The potential for addiction.
- The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

- The potential side effects of marijuana use.
- The risks, benefits, and drug interactions of marijuana.
- That the patient’s de-identified health information contained in the physician certification and registry may be used for research purposes.

### ***Issuing a Physician Certification for a Condition of the “Same Kind or Class”***

If a physician issues a certification for a condition of the same kind or class as a listed condition, the physician must provide his or her applicable board (BOM or BOOM) with additional information within 14 days after issuing the physician certification. The additional information includes:

- Documentation supporting the qualified physician’s opinion that the medical condition is of the same kind or class as the conditions enumerated.
- Documentation that establishes the efficacy of marijuana as treatment for the condition.
- Documentation supporting the qualified physician’s opinion that the benefits of medical use of marijuana would likely outweigh the potential health risks for the patient.
- Any other documentation as required by board rule.

The DOH must also submit this additional documentation to the Coalition for Medical Marijuana Research and Education (Coalition) for research purposes.

### ***Supply Limits***

A qualified physician may not issue more than three 70-day supplies of marijuana. The DOH must quantify by rule a daily dose amount for each allowable form of marijuana. A physician may request an exception to the daily dose limit by electronically submitting a form adopted by the DOH in rule to the department. At a minimum, the form must include:

- The qualified patient’s qualifying medical condition.
- The dosage and route of administration that was insufficient to provide relief to the qualified patient.
- A description of how the patient will benefit from an increased amount.
- The minimum daily dose amount of marijuana that would be sufficient for the treatment of the qualified patient’s qualifying medical condition.

A qualified physician must provide the qualified patient’s records upon the request of the department. The department must approve or disapprove the request within 14 days after receipt of the complete documentation required by this paragraph or the request is deemed approved.

### ***Patient Recertification***

A physician must recertify a patient at least once every 30 weeks. In order to recertify a patient a physician must:

- Determine if the patient still meets the requirements to be issued a physician certification.
- Identify and document in the qualified patient’s medical records whether the qualified patient experienced either of the following related to the medical use of marijuana:
  - An adverse drug interaction with any prescription or nonprescription medication; or
  - A reduction in the use of, or dependence on, other types of controlled substances as defined in s. 893.02, F.S.

- Submit a report with the findings to the department.
  - The department must send submitted reports to the Coalition.

### ***Grandfathering***

For continuity of care, any patient that was issued an order for low-THC cannabis or medical cannabis pursuant to former s. 381.986, F.S., is deemed to be a qualified patient and his or her order is deemed to be a physician certification.

### ***Physician Monitoring***

The DOH is required to monitor physician registration in the registry and the issuance of physician certifications for practices that could facilitate the unlawful diversion or misuse of marijuana and take disciplinary actions as appropriate. Additionally, the BOM and the BOOM must jointly create a physician certification review panel to review all physician certifications submitted to the registry. The review panel is required to collect specified certification data and report such data individually by physician and in the aggregate by county and statewide. Starting January 1, 2018, and annually thereafter, the panel must submit a report to the Governor and the Legislature with findings and recommendations.

### **The Medical Marijuana Use Registry**

The previously named Compassionate Use Registry is renamed the Medical Marijuana Use Registry. The DOH is required to maintain the registry for physicians, patients, and caregivers. The electronic registry must be accessible on-line to law enforcement agencies, qualified physicians, and medical marijuana treatment centers (MMTC) to verify patient certifications. The registry must also be accessible to practitioners licensed to prescribe prescription drugs to ensure proper care for patients before prescribing medications that may interact with the medical use of marijuana.

### ***Residency Requirements***

Before registering a patient with the registry, the DOH must determine whether the patient is a resident of Florida, which may include a “seasonal resident.” A “seasonal resident” includes any person who:

- Temporarily resides in this state for a period of at least 31 consecutive days in each calendar year;
- Maintains a temporary residence in this state;
- Returns to the state or jurisdiction of his or her residence at least one time during each calendar year; and
- Is registered to vote or pays income tax in another state or jurisdiction.

To prove residency a Florida resident must provide the DOH with copy of his or her valid Florida driver license or identification card. A minor must have a parent or legal guardian who meets this requirements and must also provide the DOH with a certified copy of his or her birth certificate or his or her school registration from a Florida K-12 school.



A seasonal resident who cannot provide a copy of a Florida driver license or identification card may provide the DOH with two of the following to demonstrate a residential address in this state:

- A deed, mortgage, monthly mortgage statement, mortgage payment booklet or residential rental or lease agreement.
- One proof of residential address from the seasonal resident's parent, step-parent, legal guardian or other person with whom the seasonal resident resides and a statement from the person with whom the seasonal resident resides stating that the seasonal resident does reside with him or her.
- A utility hookup or work order dated within 60 days before registration in the medical use registry.
- A utility bill, not more than 2 months old.
- Mail from a financial institution, including checking, savings, or investment account statements, not more than 2 months old.
- Mail from a federal, state, county, or municipal government agency, not more than 2 months old.
- Any other documentation that provides proof of residential address as determined by department rule.

#### ***Patient and Caregiver Disqualification***

The DOH may suspend or revoke the registration of any qualified patient or caregiver if he or she:

- Provides misleading, incorrect, false, or fraudulent information to the department;
- Obtains a supply of marijuana in an amount greater than the amount authorized by the physician certification;
- Falsifies, alters, or otherwise modifies an identification card;
- Fails to timely notify the department of any changes to his or her qualified patient status; or
- Violates the requirements of this section or any rule adopted under this section.

The DOH must suspend the registration of a qualified patient who is charged with a violation of ch. 893, F.S., until the final disposition of the offense. The DOH may revoke the registration of a qualified patient or caregiver who cultivates, acquires, possesses, or delivers marijuana that was not obtained from an MMTC. Additionally, the DOH must revoke the registration of any qualified patient and his or her caregiver if such patient no longer meets the criteria of a qualified patient.

#### **Caregivers**

In order to qualify as a caregiver an individual must:

- Not be a qualified physician and not be employed by or have an economic interest in an MMTC or a marijuana testing laboratory.
- Be 21 years of age or older and a resident of this state.
- Agree in writing to assist with the qualified patient's medical use of marijuana.
- Be registered in the medical marijuana use registry as a caregiver for no more than one qualified patient, with certain exceptions discussed below.

- Successfully complete a caregiver certification course developed and administered by the department or its designee, which must be renewed biennially. The price of the course may not exceed \$100.
- Pass a background screening, unless the patient is a close relative of the caregiver.

A qualified patient may only have one caregiver unless:

- The qualified patient is a minor and the designated caregivers are parents or legal guardians of the qualified patient;
- The qualified patient is an adult who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision and the designated caregivers are the parents or legal guardians of the qualified patient; or
- The qualified patient is admitted to a hospice program.

A caregiver may only assist one qualified patient unless:

- The caregiver is a parent or legal guardian of more than one minor who is a qualified patient;
- The caregiver is a parent or legal guardian of more than one adult who is a qualified patient and who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision; or
- All qualified patients the caregiver has agreed to assist are admitted to a hospice program and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice; and the caregiver provides personal care or other services directly to clients of the hospice in the scope of that employment.

A caregiver may not receive compensation for providing caregiver services other than actual expenses.

A caregiver must be in immediate possession of his or her medical marijuana use registry identification card at all times when in possession of marijuana or a marijuana delivery device and must present his or her card if requested by a law enforcement officer.

If a qualified patient is younger than 18 years of age, only a caregiver may purchase or administer marijuana for the patient's medical use.

### **Medical Marijuana Use Registry Identification Cards**

By August 7, 2017, the DOH is required to adopt rules for issuing medical marijuana use registry identification cards (ID cards) to qualified patients and caregivers and then begin issue ID cards to qualified patients and caregivers by October 3, 2017. The DOH may charge a reasonable fee for issuing ID cards and must allocate \$10 of the fee to the Florida Agricultural and Mechanical University for the purpose of educating minorities about marijuana for medical use and the impact of unlawful use of marijuana on minority communities. The DOH is authorized to contract with a third-party vendor to issue the identification cards. The ID cards must be resistant to tampering and counterfeiting and include, at a minimum:

- The name, address, and date of birth of the qualified patient or caregiver.

- A full-face, passport-type, color photograph of the qualified patient or caregiver taken within the 90 days immediately preceding registration or the Florida driver license or Florida identification card photograph of the qualified patient or caregiver obtained directly from the Department of Highway Safety and Motor Vehicles (DHSMV).
- Identification as a qualified patient or a caregiver.
- The unique numeric identifier used for the qualified patient in the medical marijuana use registry.
- For a caregiver, the name and unique numeric identifier of the caregiver and the qualified patient or patients that the caregiver is assisting.
- The expiration date of the identification card.

Prior to issuing an ID card to a minor, the DOH must receive written consent from the minor's parent or guardian. Patients and caregivers must return their ID cards within five business days after their registration is revoked.

## MMTCs

### *MMTC License Caps*

As soon as practicable, the DOH is required to license as an MMTC any dispensing organization (DO) that was licensed, or becomes licensed before July 1, 2017, under former s. 381.986, F.S., 2016.

The DOH is required to license 10 new MMTCs including:

- As soon as practicable, but no later than August 1, 2017, any DO applicant that:
  - Was reviewed, evaluated, and scored by the DOH;
  - Had one or more administrative or judicial challenges pending as of January 1, 2017, or that was within one point of the highest final ranking in its region under former s. 381.986, F.S., 2014;
  - Meets the requirements to be an MMTC; and
  - Can demonstrate that it has the infrastructure and the technical and technological ability to begin cultivating marijuana within 30 days after being licensed as an MMTC.
- As soon as practicable but no later than October 3, 2017, one licensee that must be a member of the Black Farmers and Agriculturalists Association-Florida Chapter, is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and that meets the requirements to be an MMTC other than the requirements to be a registered nursery and to have been a Florida business for five consecutive years prior to applying.
- Any remaining licenses must be issued by October 3, 2017.
- For up to two of the remaining licenses, the DOH is required to grant a preference to applicants that own one or more facilities that are, or were, used for the canning, concentrating, or otherwise processing of citrus fruit for market or citrus molasses and will use or convert the facility or facilities for the processing of marijuana.

Additionally, within 6 months of the registration of 100,000 qualified patients in the registry and at each additional 100,000 patients thereafter, the DOH must license four new MMTCs.

### ***Dispensary Caps***

Once licensed, each MMTC is authorized to establish a maximum of 25 dispensaries statewide. The statewide maximum number of dispensaries is increased by five per MMTC each time the registry adds 100,000 additional qualified patients. Additionally, the number of dispensaries each MMTC is authorized to establish per region<sup>52</sup> is capped based on the percentage of the total statewide population contained in that region.<sup>53</sup> The regional cap is calculated by the DOH after the completion of each decennial census.

An MMTC may sell its unused dispensing facility slots to other licensed MMTCs. After selling a slot, the seller's statewide and regional maximum number of dispensing facilities decreases by one in the region where the slot was located and the buyer's maximums increase by one. When selling a lot, both the seller and the buyer must notify the DOH of the sale.

The bill specifies that the provisions placing caps on the number of dispensaries are severable and that the provisions expire on April 1, 2020.

### ***MMTC Applications***

Applicants for licensure as an MMTC must apply on a form prescribed by the DOH. The DOH is required to charge an initial application fee and a biennial renewal fee that is sufficient to cover the costs of implementing and administering the provisions of s. 381.986, F.S., as well as ss. 381.989 and 1004.4351, F.S.<sup>54</sup> The DOH is also required to identify applicants with strong diversity plans and must provide training programs and other educational programs to enable minority persons and minority business enterprises and veteran business enterprises to compete for MMTC licensure and contracts. Each applicant for licensure must be able to demonstrate:

- That, for the 5 consecutive years before submitting the application, the applicant has been registered to do business in in the state.
- Possession of a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131, F.S.
- The technical and technological ability to cultivate and produce marijuana, including, but not limited to, low-THC cannabis.
- The ability to secure the premises, resources, and personnel necessary to operate as a MMTC.
- The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.
- An infrastructure reasonably located to dispense marijuana to registered qualified patients statewide or regionally as determined by the department.
- The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financial statements to the department.
- That all owners, officers, board members, and managers have passed a background screening.

<sup>52</sup> The regions include the northwest, northeast, central, southwest, and southeast. The bill specifies which counties are included in each region.

<sup>53</sup> For example, if the SE region contains 20 percent of the statewide population, each MMTC would only be allowed to place a maximum of 20 percent of its total dispensaries in that region.

<sup>54</sup> The bill creates s. 381.989, F.S., to establish statewide educational campaigns and s. 1004.4351, F.S., to establish the Coalition. The details of each section are included in this analysis.

- The employment of a medical director to supervise the activities of the MMTC.

In addition, each applicant must:

- Post a \$5 million performance bond issued by an authorized surety insurance company rated in one of the three highest rating categories by a nationally recognized rating service.
  - However, an MMTC serving at least 1,000 qualified patients may maintain a \$2 million performance bond.
  - In lieu of the performance bond under sub-subparagraph a., the applicant may provide an irrevocable letter of credit payable to the department or provide cash to the department. If provided with cash under this sub-subparagraph, the department shall deposit the cash with the state treasury for safekeeping. If the deposited funds generate interest, the amount of the interest shall be annually transferred to the department for the administration of this section.
- Submit a diversity plan that promotes and ensures the involvement of minority persons and minority business enterprises<sup>55</sup> or veteran business enterprises<sup>56</sup> in ownership, management, and employment.
- An applicant for licensure renewal must show the effectiveness of the diversity plan by including the following with his or her application for renewal:
  - Representation of minority persons and veterans in the MMTC's workforce;
  - Efforts to recruit minority persons and veterans for employment; and
  - A record of contracts for services with minority business enterprises and veteran business enterprises.

### ***MMTC Changes of Ownership***

A licensed MMTC may transfer ownership to an individual or entity who meets the requirements of this section including a publicly traded corporation or publicly traded company. To accommodate a change in ownership:

- The licensed MMTC shall notify the DOH in writing at least 60 days before the anticipated date of the change of ownership.
- The individual or entity applying for initial licensure due to a change of ownership must submit an application that must be received by the DOH at least 60 days before the date of change of ownership.
- The DOH must examine the application and, within 30 days after receipt, notify the applicant in writing of any apparent errors or omissions and request any additional information required.
- Requested information omitted from an application for licensure must be filed with the DOH within 21 days after the department's request for omitted information or the application shall be deemed incomplete and shall be withdrawn from further consideration and the fees shall be forfeited.
- The DOH must approve or deny the application within 30 days after the receipt of a complete application.

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<sup>55</sup> As defined in s. 288.703, F.S.

<sup>56</sup> As defined in s. 295.187, F.S.

An MMTC, and any individual or entity who directly or indirectly owns, controls, or holds with power to vote five percent or more of the voting shares of a MMTC, may not acquire direct or indirect ownership or control of any voting shares or other form of ownership of any other MMTC. An MMTC may not enter into any form of profit-sharing arrangement with the property owner or lessor of any of its facilities where cultivation, processing, storing, or dispensing of marijuana and marijuana delivery devices occurs.

### ***MMTC Requirements***

Each MMTC is required to cultivate, process, transport and dispense marijuana and an MMTC may not contract for services directly related to these functions except that an MMTC that was previously a licensed DO may contract with a single entity to perform the listed functions. Additionally, each MMTC is required to maintain compliance with the representations made in its application. The DOH may grant an MMTC a variance from such representations if the MMTC has proposed an alternative to the specific representation that will fulfill the same or similar purpose without lowering quality.

Many of the requirements that a licensed MMTC must meet are substantially similar to the current requirements for DOs. Differences include:

- MMTCs may not make a wholesale purchase or distribution of marijuana unless the MMTC submits proof of harvest failure to the DOH.
- All employees, as well as owners and managers, of an MMTC must pass a background screening.
- MMTCs are required to use the seed-to-sale tracking software that is established, maintained, and controlled by the DOH or integrate its own system with the DOH's system. The software must allow the DOH 24 hour access to the system, must allow for integration of other seed-to-sale systems, and included minimum notifications to the DOH. The DOH is authorized to contract with a vendor to produce the seed-to-sale tracking system. The contracted vendor may not have a contract to perform any other services for the DOH under s. 381.986, F.S., and may not have any direct or indirect interest in an MMTC.

### ***MMTC Cultivation Standards***

Each MMTC:

- Must grow within enclosed structure and in room separate from any other plant.
- Must comply with ch. 581, F.S., and Department of Agriculture and Consumer Services (DACS) rules regarding pest control.
- Must remove or destroy infected plants according to ch. 581, F.S., and DACS rules.
- May use DACS approved pesticides.

### ***MMTC Processing and Testing Standards***

Each MMTC must:

- Process in enclosed structure and separate room from other plants/ products.
- Not use hydrocarbon based solvents such as butane, hexane, or propane in extraction.
- Test processed marijuana before dispensing by a certified testing lab and verify testing results by two MMTC employees. The MMTC must ensure that the marijuana is safe for

human consumption and free from contaminants and must reserve 2 samples from each batch for at least nine months for testing and must contract with certified marijuana testing lab to perform audits.

- Ensure that edibles meet potency requirements.
- Ensure accurate labeling for cannabinoid potency.

### ***Packaging and Labeling Requirements***

Each MMTC must:

- Package the marijuana in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.
- Package the marijuana in a receptacle that has a firmly affixed and legible label stating the following information:
  - The marijuana or low-THC cannabis meets testing requirements.
  - The name of the MMTC from which the marijuana originates.
  - The batch number and harvest number from which the marijuana originates and the date dispensed.
  - The name of the physician who issued the physician certification.
  - The name of the patient.
  - The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products marketed by or to children.
  - The recommended dose.
  - A warning that it is illegal to transfer medical marijuana to another person.
  - A marijuana universal symbol developed by the department.
- The MMTC shall include in each package a patient package insert with information on the specific product dispensed related to:
  - Clinical pharmacology.
  - Indications and use.
  - Dosage and administration.
  - Dosage forms and strengths.
  - Contraindications.
  - Warnings and precautions.
  - Adverse reactions.
- Each edible must be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to other packaging and labeling requirements, edible receptacles must be plain, opaque, and white without depictions of the product or images other than the MMTC's department-approved logo and the marijuana universal symbol. The receptacle must also include a list all of the edible's ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

### ***Dispensing Requirements***

MMTCs may not dispense more than a 70-day supply to a qualified patient and may not dispense directly to a minor patient. Each MMTC dispensing facility must include a waiting area with

sufficient space for all qualified patients and must include at least one private consultation area that is isolated from the waiting and the dispensing areas. The MMTC may not display products in the waiting area and must ensure that all patient records are kept out of sight of anyone other than an authorized MMTC employee, the patient, or the patient's caregiver.

Each MMTC that dispenses marijuana and marijuana delivery devices must make available to the public on its website:

- Each marijuana and low-THC product available for purchase, including the form, strain of marijuana from which it was extracted, cannabidiol content, tetrahydrocannabinol content, dose unit, total number of doses available, and the ratio of cannabidiol to tetrahydrocannabinol for each product.
- The price for a 30-day, 50-day, and 70-day supply at a standard dose for each marijuana and low-THC product available for purchase.
- The price for each marijuana delivery device available for purchase.
- If applicable, any discount policies and eligibility criteria for such discounts.

### ***Advertising***

An MMTC may not engage in advertising that is visible to members of the public from any street, sidewalk, park, or other public place, except:

- The dispensing location of a MMTC may have a sign that is affixed to the outside or hanging in the window of the premises which identifies the dispensary by the licensee's business name, a department-approved trade name, or a department-approved logo. An MMTC's trade name and logo may not contain wording or images commonly associated with marketing targeted toward children or which promote recreational use of marijuana.
- An MMTC may engage in Internet advertising and marketing under the following conditions:
  - All advertisements must be approved by the department.
  - An advertisement may not have any content that specifically targets individuals under the age of 18, including cartoon characters or similar images.
  - An advertisement may not be an unsolicited pop-up advertisement.
  - Opt-in marketing must include an easy and permanent opt-out feature.

### **Background Screening Requirements**

Any individual required to undergo a background screening pursuant to s. 381.986, F.S., must pass a level II background screening as provided under ch. 435, F.S. In addition to the disqualifying offenses in ch. 435, F.S., offenses established under chs. 837,<sup>57</sup> 895,<sup>58</sup> and 896,<sup>59</sup> F.S., are also disqualifying. Fingerprints submitted to the FDLE must be retained and enrolled in the Federal Bureau of Investigation's nation retained print arrest notification program, where that program is operational.

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<sup>57</sup> Related to perjury.

<sup>58</sup> Related to racketeering and illegal debts.

<sup>59</sup> Related to financial transactions.



## Preemption

The regulation of cultivation, processing, and delivery of marijuana is preempted to the state except that a MMTC cultivation or processing facility may not be located within 500 feet of the real property of a public or private elementary, middle, or secondary school. An MMTC dispensing facility may not be located within 500 feet of a school unless the city or county approves the location through a formal proceeding in which the city or county determines that the location promotes the public health, safety, and general welfare of the community.

A county or municipality may ban MMTC dispensing facilities from being located within its borders. However, if a county or municipality allows MMTC dispensing facilities within its borders, it may not restrict the number of dispensing facilities allowed within its borders, may not enact ordinances regulating MMTC dispensing facilities that are more restrictive than its ordinances regulating pharmacies, and may not charge an MMTC a license or permit fee in an amount greater than the fee charged to pharmacies.

The bill specifies that nothing prohibits a local jurisdiction from enforcing the Florida Building Code, the Florida Fire Prevention Code, or any local amendments to such codes.

## Penalties

The bill adds additional penalties to those currently established in s. 381.986, F.S., as follows:

- A qualified patient or caregiver in possession of marijuana or a marijuana delivery device who fails or refuses to present his or her marijuana use registry identification card upon the request of a law enforcement officer commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, F.S., unless it can be determined through the medical marijuana use registry that the person is authorized to be in possession of that marijuana or marijuana delivery device.
  - A person charged with a violation of this paragraph may not be convicted if, before or at the time of his or her court or hearing appearance, the person produces in court or to the clerk of the court in which the charge is pending a medical marijuana use registry identification card issued to him or her which is valid at the time of his or her arrest. The clerk of the court is authorized to dismiss such case at any time before the defendant's appearance in court. The clerk of the court may assess a fee of \$5 for dismissing the case under this paragraph.
- A person or entity that cultivates, processes, distributes, sells, or dispenses marijuana, as defined in s. 29(b)(4), Art. X of the State Constitution, and is not licensed as a medical marijuana treatment center violates s. 893.13, F.S., and is subject to the penalties provided therein.
- A person who manufactures, distributes, sells, gives, or possesses with the intent to manufacture, distribute, sell, or give marijuana or a marijuana delivery device that he or she holds out to have originated from a licensed medical marijuana treatment center but that is counterfeit commits a felony of the third degree, punishable as provided in ss. 775.082, 775.083, or 775.084, F.S. For the purposes of this paragraph, the term "counterfeit" means marijuana; a marijuana delivery device; or a marijuana or marijuana delivery device container, seal, or label which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a licensed medical

marijuana treatment center and which thereby falsely purports or is represented to be the product of, or to have been distributed by, that licensed medical marijuana treatment facility.

- Any person who possesses or manufactures a blank, forged, stolen, fictitious, fraudulent, counterfeit, or otherwise unlawfully issued medical marijuana use registry identification card commits a felony of the third degree, punishable as provided in ss. 775.082, 775.083, or 775.084, F.S.

### **Unlicensed Activity**

If the DOH has probable cause to believe that a person or entity that is not registered or licensed has violated the provisions of s. 381.986, F.S., the DOH may issue the person or entity a cease and desist order, impose an administrative penalty of up to \$5,000 per day, and seek a civil penalty in circuit court of between \$5,000 and \$10,000. The DOH is also entitled to recover the costs of investigation and prosecution in addition to any fines levied. Any state attorney may also bring action against the violator for an injunction to restrain the unlicensed activity and the DOH must notify law enforcement of such activity.

### **Applicability**

The bill specifies that:

- The section does not limit the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy;
- The section does not require an employer to accommodate the medical use of marijuana in any workplace or any employee working while under the influence of marijuana;
- The section does not create a cause of action against an employer for wrongful discharge or discrimination.
- Marijuana, as defined in this section, is not reimbursable under ch. 440, F.S.<sup>60</sup>

**Sections 4 and 5** amend ss. 458.331 and 459.015, F.S., to include issuing physician certifications in a manner that does not comply with s. 381.986, F.S., within the grounds for licensure action for physicians licensed under chs. 458 and 459, F.S.

**Section 6** creates s. 381.988, F.S., to establish a certification program for medical marijuana testing laboratories. To be certified as a testing laboratory an applicant may not be controlled by an MMTC, must complete an application as established in rule by the DOH, must submit proof of accreditation by a certification or accreditation organization approved by the DOH, and must have all owners and managers pass a level 2 background screening with the additional offenses as detailed above. The applicant must also meet the standards for certification established by the DOH including, at a minimum:

- Security standards.
- Minimum standards for personnel.
- Sample collection method and process standards.
- Proficiency testing for tetrahydrocannabinol potency, concentration of cannabidiol, and contaminants unsafe for human consumption, as determined by department rule.
- Reporting content, format, and frequency.

<sup>60</sup> Related to worker's compensation.

- Audits and onsite inspections.
- Quality assurance.
- Equipment and methodology.
- Chain of custody.
- Any other standard the department deems necessary to ensure the health and safety of the public.

The bill also establishes acts that constitute grounds for disciplinary actions against certified marijuana testing laboratories and allows the DOH to assess penalties for violations including fines, suspending, revoking, or refusing to renew a license.

**Section 7** creates s. 381.989, F.S., to establish public education campaigns. The bill requires DOH to implement a statewide marijuana education and illicit use prevention campaign regarding the health effects of marijuana use, particularly on minors and young adults, the legal requirements for legal use and possession of marijuana and the safe use of marijuana, including preventing access by minors and those who are not qualified patients. The DOH must contract for an annual evaluation of the campaign for impact and efficacy.

The bill requires the DHSMV to implement a statewide marijuana impaired driving education campaign to raise awareness of and prevent marijuana impaired driving. The DHSMV must annually evaluate the campaign's efficacy, and may contract for that service.

**Section 15** of the bill creates a new unnumbered section of law to require the Department of Law Enforcement to develop training available to all law enforcement agencies that covers the legal parameters of marijuana-related activities by qualified patients, caregivers, MMTCs, and medical marijuana testing labs.

**Section 11** creates s. 1004.4351, F.S., to create the Medical Marijuana Research and Education Act. The act:

- Establishes the Coalition for Medicinal Cannabis Research and Education (Coalition) within the H. Lee Moffitt Cancer Center and Research Institute, Inc. (MCCRI) and provides that the Coalition's purpose is to conduct rigorous scientific research, provide education, disseminate research, and to guide policy development for the adoption of a statewide policy on ordering and dosing practices for the medicinal use of cannabis.
  - Beginning January 15, 2018, the DOH must submit quarterly to the Medicinal Cannabis Research and Education Board (Board) or coalition information for each patient registered with the compassionate use registry, including the patient's debilitating medical condition, the amount and duration of the patient's marijuana recommendation, the method of marijuana administration and any delivery device, and the patient's certifying physician.
  - The coalition must review these data and determine whether state law and rules should be modified to address abuse or fraud of the system established in Article X, section 29 of the State Constitution, and state law and rules, and if so, must include recommendations to address such abuse or fraud.
- Creates the board to direct the Coalition's operations. Additionally, the bill specifies Board membership requirements and requires the Board to:

- Advise the Board of Governors, the State Surgeon General, the Governor, and the Legislature with respect to medicinal cannabis research and education in Florida.
- Explore methods of implementing and enforcing medicinal cannabis laws in relation to cancer control, research, treatment, and education.
- Annually adopt a plan for medicinal cannabis research, known as the Medicinal Cannabis Research and Education Plan (Plan) in accordance with state law, and must include recommendations for the coordination and integration of medical, nursing, paramedical, community, and other resources connected with the treatment of debilitating medical conditions, research related to the treatment of such conditions, and education.
- Issue an annual report, by February 15, to the Governor, the President of the Senate, and the Speaker of the House Representatives on research projects, community outreach initiatives, and future plans for the Coalition.
- Provides that the Coalition must be administered by a director who, subject to Board approval, must:
  - Propose a budget.
  - Foster the collaboration of scientists, researchers, and other appropriate personnel.
  - Identify and prioritize the Coalition's research.
  - Prepare the Plan for submission to the Board.
  - Apply for grants to obtain funding for the Coalition's research.
  - Perform other Board specified duties.
- Requires the MCCRI to allocate staff, information, and assistance to assist the Board.

**Section 13** amends s. 1006.062, F.S., to require each school board to adopt a policy and procedure for allowing a student who is a qualified patient to medically use his or her marijuana in school.

**Section 14** creates a new unnumbered section of law.

### **Implementation/Rulemaking**

The bill grants DOH and the applicable boards limited emergency rulemaking authority in order for DOH to meet the rulemaking deadlines imposed by s. 29, Art. X of the State Constitution. The bill allows DOH and the applicable boards to adopt emergency rules necessary to implement the bill. The bill allows DOH and the applicable boards to adopt emergency rules to replace any emergency rules that were held to be an invalid delegation of legislative authority or unconstitutional. However, the bill prohibits DOH and the applicable boards from adopting emergency rules to replace those emergency rules if they are also held to be an invalid delegation of legislative authority or unconstitutional. The bill requires DOH and the applicable boards to begin replacing the emergency rules by January 1, 2018.

The bill also exempts DOH and the applicable boards from the statement of regulatory costs requirements and the emergency rulemaking requirement that there is an immediate danger to the public health, safety, or welfare which requires emergency action. The bill also exempts the emergency rules from the 90 day effective date and allows the emergency rules to remain in effect until replaced through non-emergency rulemaking procedures by DOH and the applicable boards.

### **Cause of Action**

The bill also establishes the Circuit Court in and for Leon County as the venue for any cause of action brought under s. 29, Art. X of the State Constitution due to DOH's failure to meet the rulemaking deadlines imposed by s. 29, Art. X of the State Constitution. The bill specifies that the judicial relief for such cause of action shall be an action for a declaratory judgment pursuant to ch. 86, F.S. The bill also provides affirmative defenses to DOH for a cause of action brought under s. 29, Art. X of the State Constitution due to DOH's failure to meet the rulemaking deadlines.

**Section 17** creates a new unnumbered section of law to specify that the provisions of the act are severable.

**Section 18** creates a new unnumbered section of law to direct the Division of Law Revision and Information to replace the phrase "the effective date of this act" with the actual effective date.

**Section 19** creates a new unnumbered section of law to establish specific appropriations as follows:

The bill appropriates 55 full-time equivalent (FTE) positions, \$3,500,000 in nonrecurring funds from the General Revenue Fund and \$4,055,292 in recurring and \$1,238,148 in nonrecurring funds from the Grants and Donations Trust Fund to the DOH for the purpose of implementing the requirements of this act. Of these funds, \$3,158,572 in recurring and \$1,238,148 in nonrecurring funds from the Grants and Donations Trust Fund and 27 FTE positions are placed in reserve. The DOH may submit a budget amendment requesting release of these funds contingent upon need and demonstrating fee collections to support the budget authority.

The bill appropriates \$500,000 in nonrecurring funds from the General Revenue Fund to the DOH to implement the statewide marijuana education and use prevention campaign.

The bill appropriates \$5,000,000 in nonrecurring funds from the Highway Safety Operating Trust Fund to the DHSMV to implement the impaired driving education campaign.

The bill appropriates \$100,000 in recurring funds from the Highway Safety Operating Trust Fund to the DHSMV for the purpose of training additional law enforcement officers as drug recognition experts.

The bill also appropriates \$750,000 in nonrecurring General Revenue funds for the Coalition to conduct medical cannabis research.

**Sections 8, 9, 10, 12, and 16** make conforming changes to ss. 385.211, 499.0295, 893.02, 1004.441, and 385.212, F.S., respectively.

**Section 20** of the bill specifies that the provisions in the act take effect upon becoming law.

**IV. Constitutional Issues:****A. Municipality/County Mandates Restrictions:**

None.

**B. Public Records/Open Meetings Issues:**

None.

**C. Trust Funds Restrictions:**

None.

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

MMTCs will likely incur costs associated with licensure and meeting the regulatory standards required by the bill. Marijuana testing laboratories may incur additional costs to become certified by DOH.

MMTCs and marijuana testing laboratories will incur costs associated with the required background screenings. The total cost for a state and national criminal history record check with fingerprint retention for 5 years by FDLE is \$60.

**C. Government Sector Impact:**

The DOH and other state agencies will likely incur an indeterminate negative fiscal impact related to the implementation of the provisions of the bill and the regulatory requirements of the bill. These costs will likely be offset or eliminated through licensure fees for MMTCs and through fees assessed for issuing ID cards.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 212.08, 381.986, 458.331, 459.015, 385.211, 499.0295, 893.02, 1004.441, 1006.062, and 385.212.

This bill creates the following sections of the Florida Statutes: 381.988, 381.989, 1004.4351 and six new unnumbered sections of Florida law.

**IX. Additional Information:**

- A. **Committee Substitute – Statement of Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

- B. **Amendments:**

**Barcode 606998 by Health Policy**

This is a technical title amendment to accurately reflect the substance of the bill. It removes reference to expiration of the sales tax exemption.

**Barcode 501070 by Health Policy**

Specifies that cash deposited with the DOH (in lieu of the \$5 million bond that MMTC license holders are required to post) must be deposited in the Grants and Donations Trust Fund and specifies that any interest earned on such deposits must be used by the DOH for the administration of the medical marijuana program.

**Barcode 633510 by Health Policy**

Requires, rather than merely authorizing, the DOH to contract with a vendor to issue qualified patient and caregiver registration identification cards.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



**Ron DeSantis**  
Governor

**Vision:** To be the Healthiest State in the Nation

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January 22, 2019

Via Email Delivery To: SMF@phrd.com

Seann M. Frazier  
Parker Hudson Rainer & Dobbs  
215 South Monroe Street  
Suite 750  
Tallahassee, Florida 32301

Mr. Frazier

This responds to your letter addressed to the Department of Health's Agency Clerk on January 17, 2019, regarding Louis Del Favero Orchids, Inc. (Del Favero).

On October 8, 2018, the Department received a three-page letter from you on behalf of Del Favero requesting registration as a Medical Marijuana Treatment Center pursuant to Article X, Section 29, of the Florida Constitution. Nothing additional accompanied that letter. Then, on October 17, 2018, the Department received what Del Favero purported to be an application for registration as a Medical Marijuana Treatment Center containing information purporting to comply with the Department's Constitutional Regulation 2-1.01. A check for \$60,830.00 was also enclosed.

Within the Constitutional Regulation, the Department specifically and expressly provided that it would publish notice to the public of when the Department will begin accepting applications along with a deadline to submit applications for registration as a Medical Marijuana Treatment. No such dates or deadlines have been published by the Department yet. Thus, there has not been, nor is there any, open application period. Accordingly, Del Favero's purported application was premature, untimely, and did not trigger any obligation for the Department to take action.

Your letter purports to give notice under section 120.60(1), Florida Statutes, of Del Favero's intent to rely on default licensure. Because Del Favero's request was made pursuant to Article X, Section 29 of the Florida Constitution, chapter 120, Florida Statutes, is entirely inapplicable. Any argument to the contrary is erroneous and contradicts Del Favero's representations to the Circuit Court of the Second Judicial Circuit in paragraph 31 of Del Favero's Complaint in case number 2017-CA-2549.

Furthermore, on May 1, 2018, the Department attempted to adopt proposed Rule 64-4.002, Florida Administrative Code, to implement its statutory obligations under section 381.986, Florida Statutes. Although that proposed rule was obviously subject to the provisions of chapter 120, Florida Statutes, your client, Del Favero, filed a petition challenging the validity of that proposed rule on June 1, 2018 -- well before your client attempted to gain licensure through the Constitutional Regulation in

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**Florida Department of Health**  
**Office of the General Counsel**  
4052 Bald Cypress Way, Bin A-02 • Tallahassee, FL 32399-1701  
PHONE: 850/245-4005 • FAX: 850/413-8743  
**FloridaHealth.gov**



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October 2018. Because that proposed rule is currently the subject of an ongoing rule challenge proceeding, it was not filed for adoption and has not become effective.

It is worth noting that cannabis remains illegal in Florida and cannot be grown, processed, dispensed, or sold, in this state unless approved by the Department and within the confines of applicable law. Del Favero does not hold any license or other registration under section 381.986, Florida Statutes, or any other law and therefore is not authorized or approved by the Department to operate as a Medical Marijuana Treatment Center. Del Favero should govern itself accordingly.

Sincerely,

A handwritten signature in black ink, appearing to read "Louise Wilhite-St Laurent", written in a cursive style.

Louise Wilhite-St Laurent  
General Counsel